Closed Grant File

TABLE OF CONTENTS

SECTIONS

GRANT SUMMARY

Grant Summary
ID# 036509

Awarded 07/30/99 - Closed 12/27/02

University of Wisconsin-Madison Medical School (Madison,WI)

Program: (EOL)Targeted End-of-Life Projects Initiative

Project Title: A project to assess states' pain policies

Project Director: David E. Joranson M.S.S.W. (608-263-7662)

Duration: 33 Months: 08/01/99 to 04/30/02

Team: END OF LIFE

Funding Class:	NP Implementation	**Amount:**	998,000
New/Renewal:		**Actual Amount:**	965,493
Renewed by:	043412	**Program Indicator:**	In Program
Funding Type:	N/A	**Precis Checked In:**	Yes
Request Type:	Solicited		
Meets Objective:	Yes		

Goals: CHR(100%)
Interventions: Rsrch & Pol Anal(100%)

Board Date: 10/99 **Board Class:** B **Board Page:** 334

PO: Gibson, Rosemary
SO: Gibson, Rosemary
PA: Stives, Jeanne M.
FA: Kounelias, Sophia

GIS Summary

The Robert Wood Johnson Foundation's Targeted End-of-Life Projects initiative will support projects that advance the Foundation's three strategic objectives to improve care at the end of life: (1) to improve the knowledge and capacity of health care professionals and others to care for the dying; (2) to improve the institutional environment in health care institutions and in public policies and regulatory apparatus to enable better care of the dying; and (3) to educate the public about the kind of care they should come to expect at the end of life

Pain policy is a new arena for many state legislators and other policy makers. To help fill the gap in understanding state pain policy, the purpose of this project is to conduct the first state-by-state assessment of states' laws, regulations, and guidelines regarding the treatment of pain with controlled substances. In addition, the project will highlight specific examples of improvements that states have made in their pain policies to help inform other states about

positive changes that can be made and thereby facilitate progressive pain policy in other states. Changes in state policies also will be continuously tracked. Additionally, the Pain and Policy Studies Group will provide technical assistance to grantees in the Foundation's national initiative and to the increasing number of health and government organizations including state medical boards that are developing pain management and end-of-life initiatives. Finally, consistent with the intent of increasing the awareness of pain policy issues and the ability of key individuals and organizations in government and health care to evaluate and improve polices that affect pain management, there will be a proactive outreach component.

Health Service Category

Continuum of Care:	End Of Life
	Treatment
Health Care Reform:	State
Pharmaceutical Services:	Pharmaceutical Services

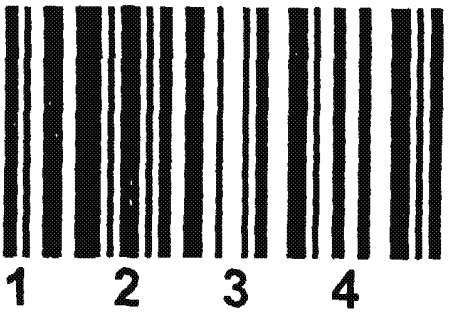
Demographics

Age:	65 & over - Aging/Elderly/Senior Citizens
	N/A
Geographic Region:	N/A
Major City:	Unknown, N/A or N/S
Race/Ethnicity:	N/A
Segment:	N/A
Sex:	N/A
State:	Unknown, N/A or N/S
Urban/Rural Continuum:	Unknown, N/A or N/S

SECTION

1

GRANT DESCRIPTION



GRANT DESCRIPTION - OBJECTIVES AND DESIGN

ID#: 036509 (Closed) $998,000.00
TERM: 33 MONTHS **FROM** 08/01/99 **TO** 04/30/02 (GRANTED 07/30/99)

FUNDING CLASS: NP - Implementation Site
RENEWED FROM: 035950 **RENEWED AS:** 043412

PROG: Targeted End-of-Life Projects Initiative (EOL)

INST: University of Wisconsin-Madison Medical School (Madison,WI)

PRJT: A project to assess states' pain policies

PRJ DIR: David E. Joranson

PO: Rosemary Gibson
SO: Rosemary Gibson
PA: Jeanne M. Stives
FO: Sophia Kounelias

RISK: Low
DATE COMPLETED: 07/23/99
PREPARED BY: LLM

The Robert Wood Johnson Foundation's Targeted End-of-Life Projects initiative will support projects that advance the Foundation's three strategic objectives to improve care at the end of life: (1) to improve the knowledge and capacity of health care professionals and others to care for the dying; (2) to improve the institutional environment in health care institutions and in public policies and regulatory apparatus to enable better care of the dying; and (3) to educate the public about the kind of care they should come to expect at the end of life

Pain policy is a new arena for many state legislators and other policy makers. To help fill the gap in understanding state pain policy, the purpose of this project is to conduct the first state-by-state assessment of states' laws, regulations, and guidelines regarding the treatment of pain with controlled substances. In addition, the project will highlight specific examples of improvements that states have made in their pain policies to help inform other states about positive changes that can be made and thereby facilitate progressive pain policy in other states. Changes in state policies also will be continuously tracked. Additionally, the Pain and Policy Studies Group will provide technical assistance to grantees in the Foundation's national initiative and to the increasing number of health and government organizations including state medical boards that are developing pain management and end-of-life initiatives. Finally, consistent with the intent of increasing the awareness of pain policy issues and the ability of key individuals and organizations in government and health care to evaluate and improve polices that affect pain management, there will be a proactive outreach component.

Goals: Chronic(100%)

Health Service Category:

Continuum of Care:	*End Of Life Treatment*
Health Care Reform:	*State*
Pharmaceutical Services:	*Pharmaceutical Services*

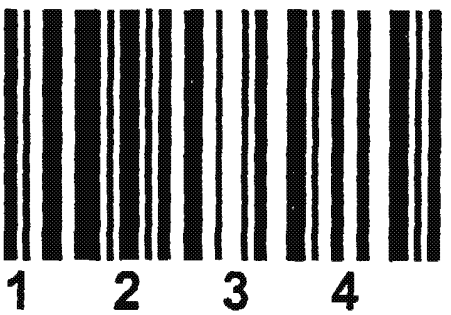
Demographics:

Age:	*65 & over - Aging/Elderly/Senior Citizens*
	Not Applicable
Race/Ethnicity:	*Not Applicable*
Sex:	*Not Applicable*
Segment:	*Not Applicable*
Geographic Region:	*Not Applicable*
Urban/Rural Continuum:	*Unknown, Not Applicable, or Not Specified*
Major City:	*Unknown, Not Applicable, or Not Specified*
State:	*Unknown, Not Applicable, or Not Specified*

SECTION

2

GRANT RESULTS REPORT



ITEM

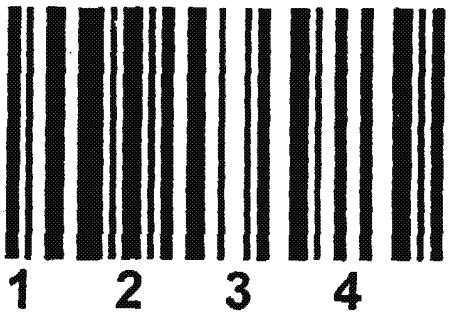
NOT

SUBMITTED

SECTION

3

REQUEST FOR PROJECT SUPPORT & AMENDMENT TAX PAPERS



PAIN & POLICY STUDIES GROUP

WHO Collaborating Center
for Policy and Communications
in Cancer Care

July 18, 2001

The Robert Wood Johnson Foundation
Route 1 and College Road East
Post Office Box 2316
Princeton, New Jersey 08543-2316

To Whom It May Concern:

This letter is to notify you that effective as of June 28, 2001 David Joranson's new mailing address is:

Pain & Policy Studies Group
406 Science Dr., Suite 202
Madison WI 53711-1068

Please change your records to reflect this change. Thank you!

Sincerely,

Linda Gorman

Linda Gorman
Program Assistant
University of Wisconsin-Madison
Pain & Policy Studies Group
406 Science Drive, Suite 202
Madison, WI 53711-1068

3600

THE ROBERT WOOD JOHNSON FOUNDATION

DO NOT SEPARATE THIS DOCUMENT

Route 1 and College Road East
P.O. Box 2316
Princeton, NJ 08543-2316
(609) 452-8701

THE ROBERT WOOD JOHNSON FOUNDATION

JAN 28 1999

ANSWERED | RECORDED | DATA SHEET

Request for Project Support and Conditions of Grant

Title of Project:
Building Capacity to Promote Pain Policy Through Evaluation, Research, and Communication

Purpose of Project: This project will accomplish a systematic and comprehensive state-by-state evaluation of pain-related policies and communicate the results in ways to increase the capacity of others to understand.

Applicant Institution (name, address, and telephone number):
University of Wisconsin ~~System~~ Madison Medical School
750 University Avenue
Madison WI 53706

(608) 262-0152

mw 7/24/99

Check to be Made Payable to:
University of Wisconsin ~~Board of Regents~~
mw 7/24/99

Institutional Financial Officer (full name, title, address, telephone number, and fax number):
August P. Hackbart
Administrative Officer
750 University Avenue
Madison WI 53706

(608) 262-0152
FAX (608) 262-5111

Amount of Support Requested (total project period):
~~$1,823,391~~ $998,000. mH 7/29/99

Period for Which Support is Requested (total project period):
From ~~05-01-99~~ 8/1/99 Through ~~04-30-02~~ 1/31/02
Month Day Year Month Day Year

mH 7/29/99

*Project Director (full name, title, address, telephone number, and fax number):
David E. Joranson, MSSW
Senior Scientist, Director
Pain & Policy Studies Group
1900 University Avenue
Madison WI 53705-4013

(608) 263-7662 FAX (608) 263-0259

(NOTE. Signature required on page 4)

Applicant Institutional Approval (full name, title, and address of official authorized to sign for institution):
August P. Hackbart
Administrative Officer
750 University Avenue
Madison WI 53706

(NOTE: Signature required on page 4)

Please provide the following evidence of your institution's tax status:

If your institution is a tax-exempt organization described in Section 501(c)(3) of the Internal Revenue Code, (i) a copy of the letter your institution received from the Internal Revenue Service stating that your institution is exempt from taxation by virtue of being described in Section 501(c)(3); (ii) a copy of the letter your institution received from the Internal Revenue Service stating that either your institution is not a private foundation described in Section 509(a) or stating that your institution is an exempt operating foundation described in Section 4940(d)(2); and (iii) a copy of Form 4653 or Form 1023 and other data, if any, your institution has filed with or received from the Internal Revenue Service concerning your tax status.

If your institution is an organization described in Section 170(c)(1) or Section 511(a)(2)(B) of the Internal Revenue Code, (i) a copy of the correspondence, if any, from the Internal Revenue Service stating that fa or (ii) a copy of the legislation establishing your institution.

These documents must be accompanied by a letter signed by a responsible officer of your institution certifying that the copies so provided are true and correct copies of the originals on file with your institution and that they remain in full force and effect.

Any questions you may have about your tax-exempt status should be directed to the Office of the Vice President, General Counsel and Secretary (609-243-5908).

TAX PAPERS APPROVED Signature Date 7/29/99

*The project director is the individual directly responsible for developing the proposed activity, its implementation, and day-to-day direct supervision of the project should funds be made available.

RWJF (03/95) – PUBLIC ENTITIES AND EXEMPT OPERATING FOUNDATIONS [DESCRIBED IN SECTION 4940(d)(2) OF THE INTERNAL REVENUE CODE]

CONDITIONS OF GRANT

Following are the conditions applying to grants made by The Robert Wood Johnson Foundation ("the Foundation"). You should read these conditions carefully prior to signing this form. Your signature on this form constitutes your acceptance in full of all conditions contained herein. To induce the Foundation to make the grant requested hereby, you ("the grantee") accept and agree to comply with the following conditions in the event that such grant is awarded. As used throughout this form, the term "grant" shall include the income, if any, arising therefrom unless the context otherwise requires.

1. **PURPOSE AND ADMINISTRATION.** The grant shall be used exclusively for the purposes specified in the grantee's proposal, dated 1-26-99, the Request for Project Support Form on page 1 hereof, and related documents, all as approved by the Foundation.

   The grantee will directly administer the project or program being supported by the grant and agrees that no grant funds shall be disbursed to any organization or entity, whether or not formed by the grantee, other than as specifically set forth in the grant proposal referred to above.

2. **USE OF GRANT FUNDS.**

   A. No part of the grant shall be used to carry on propaganda or otherwise attempt to influence legislation [within the meaning of Section 4945(d)(1) of the Internal Revenue Code].

   B. No part of the grant shall be used to attempt to influence the outcome of any specific public election or to carry on, directly or indirectly, any voter registration drive [within the meaning of Section 4945(d)(2) of the Internal Revenue Code].

   C. No part of the grant shall be used to provide a grant to an individual for travel, study, or similar purpose without complying with the requirements of Section 4945(g) of the Internal Revenue Code as if the grant were made by the Foundation and without prior written approval of the Foundation. Payments of salaries, other compensation, or expense reimbursement to employees of the grantee within the scope of their employment do not constitute "grants" for these purposes and are not subject to these restrictions.

   D. No part of the grant shall be used for a grant to another organization without complying with the requirements of Section 4945(d)(4) and, if applicable, Section 4945(h) of the Internal Revenue Code as if the grant were made by the Foundation and without prior written approval of the Foundation.

   E. No part of the grant shall be used for other than religious, charitable, scientific, literary, or educational purposes or the prevention of cruelty to children or animals [within the meaning of Section 170(c)(2)(B) of the Internal Revenue Code].

   F. The grantee promptly shall repay any portion of the grant which for any reason is not used exclusively for the purposes of the grant. The grantee shall repay to the Foundation any portion of the grant which is not used exclusively for the purposes described in Section 1 hereof within the time specified in the grantee's proposal or within any approved extension of said time period within fifteen (15) days after such specified time or such extension. If the Foundation terminates the grant pursuant to Section 10 hereof, the grantee shall repay within thirty (30) days after written request by the Foundation all grant funds unexpended as of the effective date of termination and all grant funds expensed for purposes or items allocable to the period of time subsequent to the effective date of termination. In the event that any portion of the grant is used for purposes other than those described in Section 170(c)(2)(B) of the Internal Revenue Code, the grantee shall repay to the Foundation that portion of the grant as well as any additional amount in excess of such portion necessary to effect a correction under Section 4945 of the Internal Revenue Code.

   G. If the grantee is directly or indirectly controlled by the Foundation or by one or more "disqualified persons" (within the meaning of Section 4946) with respect to the Foundation, the grantee agrees (i) to expend all of the grant prior to the grantee's first annual accounting period following the taxable year in which the grantee receives a grant payment, thereby permitting the Foundation to count the grant as a qualifying distribution under Section 4942(g)(3) and (h); and (ii) to submit to the Foundation promptly after the close of the grantee's annual accounting period a full and complete written report signed by an appropriate officer, director, or trustee, showing that the qualifying distribution has been made, the name and address of the recipient or recipients, the amounts received by each, and that all the distributions are treated as distributions out of corpus.

3. **BUDGET.** Expenditures of the grant funds must adhere to the specific line items in the grantee's approved grant budget. Transfers among line items (increases and decreases) are permitted under the conditions and to the extent indicated in the Foundation's Budget Preparation Guidelines in effect at the time of any such proposed transfer, and such Budget Preparation Guidelines in their entirety, and as they may be modified by the Foundation from time to time, are incorporated herein by this reference.

4. **ACCOUNTING AND AUDIT.** The grantee shall indicate the grant separately on its books of account. A systematic accounting record shall be kept by the grantee of the receipt and disbursement of funds and

expenditures incurred under the terms of the grant, and the substantiating documents such as bills, invoices, cancelled checks, and receipts, shall be retained in the grantee's files for a period of not less than four (4) years after expiration of the grant period. The grantee agrees promptly to furnish the Foundation with copies of such documents upon the Foundation's request.

The grantee agrees to make its books and records available to the Foundation at reasonable times.

The Foundation, at its expense, may audit or have audited the books and records of the grantee insofar as they relate to the disposition of the funds granted by the Foundation, and the grantee shall provide all necessary assistance in connection therewith.

5. **REPORTS**. Narrative and financial reports shall be furnished by the grantee to the Foundation for each budget period of the grant and upon expiration, repayment (pursuant to Section 2F hereof), or termination of the grant (pursuant to Section 10 hereof). Such reports shall be furnished to the Foundation within a reasonable period of time after the close of the period for which such reports are made. The narrative report shall include a report on the progress made by the grantee towards achieving the grant purposes and any problems or obstacles encountered in the effort to achieve the grant purposes. The financial report shall show actual expenditures reported as of the date of the report against the approved line item budget. Such reports shall be retained in the grantee's files for a period of not less than four (4) years after expiration of the grant period.

   The Foundation may, at its expense, monitor and conduct an evaluation of operations under the grant, which may include visits by representatives of the Foundation to observe the grantee's program procedures and operations and to discuss the program with the grantee's personnel.

6. **COPYRIGHT, FOUNDATION USE OF DATA, AND PUBLIC USE DATA TAPES**. Except as may otherwise be provided in Section 12 hereof, all copyright interests in materials produced as a result of this grant are owned by the grantee. The grantee hereby grants to the Foundation a nonexclusive, irrevocable, perpetual, royalty-free license to reproduce, publish, copy, alter, or otherwise use and to license others to use any and all such materials, including any and all data collected in connection with the grant in any and all forms in which said data are fixed. If the box below is checked, the grantee shall, at no additional cost to the Foundation, cause public use data tape(s) to be constructed (with appropriate adjustments to assure individual privacy) in accordance with the specifications of the Inter-University Consortium for Political and Social Research, University of Michigan, including the full tape documentation outlined in the Consortium's current data preparation manual. Unless the Foundation shall otherwise specify, such public use data tape(s) shall include all data files used to conduct the analysis under the grant. The grantee shall transmit one computer-readable copy of such public use data tape(s) and the tape documentation to the Consortium upon expiration of the grant period.

   ☐ Public use data tape(s) and full documentation required.

7. **PUBLIC REPORTING**. The Foundation will report this grant, if made, in its next Annual Report. The Foundation does not usually issue press releases on individual grants; however, should the Foundation elect to do so, it would discuss the press release with the grantee in advance of dissemination. The grantee may issue its own press announcement but shall seek approval of the announcement from the Foundation before distribution. In addition, the grantee will be asked to review and approve a Program Summary briefly describing the grantee's activity which will be used by the Foundation to respond to inquiries and for other public information purposes. The grantee's approval shall not be unreasonably withheld.

   The grantee shall send to the Foundation copies of all papers, manuscripts, and other information materials which it produces that are related to the project supported by the Foundation.

   In all public statements concerning the Foundation – press releases, annual reports, or other announcements – the grantee is specifically requested to refer to the Foundation by its full name: The Robert Wood Johnson Foundation.

8. **GRANTEE TAX STATUS**. The grantee represents that it is currently either (i) a tax-exempt entity described in Section 501(c)(3) of the Internal Revenue Code and either (a) is not a private foundation described in Section 509(a), or (b) is an exempt operating foundation described in Section 4940(d)(2); or (ii) an organization described in Section 170(c)(1) or Section 511(a)(2)(B). The grantee shall immediately give written notice to the Foundation if the grantee ceases to be exempt from federal income taxation as an organization described in Section 501(c)(3) or its status as not a private foundation under Section 509(a), as an exempt operating foundation described in Section 4940(d)(2), or as a Section 170(c)(1) or Section 511(a)(2)(B) organization is materially changed.

9. **CERTIFICATION REQUIRED WHEN GRANT MAY BE USED FOR RESEARCH INVOLVING HUMAN SUBJECTS**. If the grant is to be used in whole or in part for research involving human subjects, the grantee hereby certifies that the grantee, applying the ethical standards and the criteria for approval of grants set forth in Department of Health and Human Services policy for the protection of human research

subjects (45 CFR part 46, as amended from time to time), has determined that the human subjects involved in this grant will not experience risk over and above that involved in the normal process of care and are likely to benefit from the proposed research program.

10. **GRANT TERMINATION.** It is expressly agreed that any use by the grantee of the grant proceeds for any purpose other than those specified in Section 170(c)(2)(B) of the Internal Revenue Code will terminate the obligation of the Foundation to make further payments under the grant.

    The Foundation, at its sole option, may terminate the grant at any time if (i) the grantee ceases to be exempt from federal income taxation as an organization described in Section 501(c)(3) of the Internal Revenue Code; (ii) the grantee's status as not a private foundation under Section 509(a), its status as an exempt operating foundation under Section 4940(d)(2), or its status as a Section 170(c)(1) or Section 511(a)(2)(B) organization is materially altered; or (iii) in the Foundation's judgment, the grantee becomes unable to carry out the purposes of the grant, ceases to be an appropriate means of accomplishing the purposes of the grant, or fails to comply with any of the conditions hereof.

    If the grant is terminated prior to the scheduled completion date, the grantee shall, upon request by the Foundation, provide to the Foundation a full accounting of the receipt and disbursement of funds and expenditures incurred under the grant as of the effective date of termination.

11. **LIMITATION; CHANGES.** It is expressly understood that the Foundation by making this grant has no obligation to provide other or additional support to the grantee for purposes of this project or any other purposes. Any changes, additions, or deletions to the conditions of the grant must be made in writing only and must be jointly approved by the Foundation and the grantee.

12. **SPECIAL CONDITIONS.** The grantee accepts and agrees to comply with the following Special Conditions (if no Special Conditions are imposed, so state):

The foregoing conditions are hereby accepted and agreed to as of the date indicated.

Date: 1-27-99 Grantee Institution: University of Wisconsin System

By: August P. Hackbart
(Signature of Authorized Official)

Title: Administrative Officer

Date: 26 Jan 99 By: David E Johnson
(Signature of Project Director)

36509

PAIN & POLICY STUDIES GROUP

WHO Collaborating Center
for Policy and Communications
in Cancer Care

THE ROBERT WOOD JOHNSON FOUNDATION

JAN 28 1999

ANSWERED | RECORDED | DATA ENTERED

January 26, 1999

Rosemary Gibson
Senior Program Officer
The Robert Wood Johnson Foundation
Route One and College Road East
Princeton, NY 08543-2316

Dear Ms. Gibson:

On behalf of the Pain & Policy Studies Group at the University of Wisconsin-Madison, we are requesting funding in the amount of ~~$1,823,391~~ $998,000. MH 7/29/99 for the project, *Building Capacity to Promote Pain Policy Through Evaluation, Research and Communication*, under the direction of David E. Joranson.

The attached copies of our tax documentation are true and correct copies of the originals on file with our institution and they remain in full force and effect.

The administrative officer of our organization is:

August Hackbart
Administrative Officer
University of Wisconsin System
750 University Avenue
Madison, WI 53706
(608) 262-0152

Sincerely,

David E. Joranson

David E. Joranson, MSSW
Senior Scientist, Director

August L. Hackbart

August Hackbart
Administrative Officer

Enclosures

UW Comprehensive Cancer Center - University of Wisconsin-Madison Medical School
1900 University Avenue Madison, WI 53705 USA (608) 263-7662 FAX: (608) 263-0259

Department of the Treasury

Internal Revenue Service
Washington, DC 20224

Date: 12-24-70 | In reply refer to:

THE UNIVERSITY OF WISCONSIN
1956 VAN HISE HALL 1220 LINDEN DR
MADISON, WI 53706

Gentlemen:

Based on the information you recently submitted, we have classified you as an organization that is not a private foundation as defined in section 509(a) of the Internal Revenue Code.

Your classification is based on the assumption that your operations will be as stated in your notification. Any changes in your purposes, character, or method of operation must be reported to your District Director so he may consider the effect on your status.

Sincerely yours,

J. A. Veales

Chief, Rulings Section
Exempt Organizations Branch

FORM M-0714 (8-70) (CONTINUOUS)

Form 4653
(June 1970)
Department of the Treasury
Internal Revenue Service

Notification Concerning Foundation Status

Do not write in this space (For IRS use only)
☐ Classification code
☐ Letter code

Please print or type

Name of organization: The University of Wisconsin

Employer Identification Number: 39-6006492

Number and street: 1856 Van Hise Hall, 1220 Linden Drive

City or town, State and ZIP code: Madison, Wisconsin 53706

Please place an "X" in the one numbered block that applies to your organization, provide any additional information called for, and return the form promptly to the Internal Revenue Service Center, 11601 Roosevelt Boulevard, Philadelphia Pennsylvania 19155. Do not check a block until you have read the instructions and Code definitions applicable to that block. Section references are to the Internal Revenue Code of 1954.

1 ☐ We are a private foundation within the meaning of section 509(a). (If you are a private foundation, are you claiming status as an operating foundation within the meaning of section 4942(j)(3)? . . . ☐ Yes ☐ No If "Yes," attach a statement setting forth all the facts upon which you base your answer including an identification of the clause of section 4942(j)(3)(B) that is applicable

We are not a private foundation because we are:

2 ☐ A church. Section 170(b)(1)(A)(i).

3 ☒ A school. Section 170(b)(1)(A)(ii).

4 ☐ A hospital. Section 170(b)(1)(A)(iii).

5 ☐ A medical research organization operated in conjunction with a hospital. Section 170(b)(1)(A)(iii).

6 ☐ A Governmental unit. Section 170(b)(1)(A)(v).

7 ☐ An organization operated for the benefit of a college or university owned or operated by a Governmental unit. Section 170(b)(1)(A)(iv).

(Complete the Financial Schedule on page 2.)

8 ☐ An organization that normally receives a substantial part of its support from a Governmental unit or from the general public. Section 170(b)(1)(A)(vi).

(Complete the Financial Schedule on page 2.)

9 ☐ An organization that normally receives no more than ⅓ of its support from gross investment income and more than ⅓ of its support from contributions, membership fees, and gross receipts from activities related to its exempt functions—subject to certain exceptions. Section 509(a)(2).

(Complete the Financial Schedule on page 2.)

10 ☐ An organization operated solely for the benefit of and in connection with one or more of the organizations described in 2 through 9 (or for the benefit of one or more organizations described in section 501(c)(4), (5), or (6) and also described in 9 above), but not controlled by disqualified persons other than foundation managers. Section 509(a)(3).

(Attach a statement identifying and describing the organization(s) for whose benefit you are operated and the relationship between you and the organization(s).)

11 ☐ An organization organized and operated to test for public safety. Section 509(a)(4).

12 ☐ We are not sure of our classification.
(Attach a copy of your most recently filed information return, Form 990-A, if you filed one, and a statement describing your operations and explaining why you are not sure of your classification. If you think you may be described in 7, 8, or 9, complete the Financial Schedule on page 2.)

I declare that I have examined the information entered on this form, including accompanying schedules and statements, and to the best of my knowledge and belief, it is true, correct and complete. (Must be signed by a principal officer, manager, or authorized trustee of the organization.)

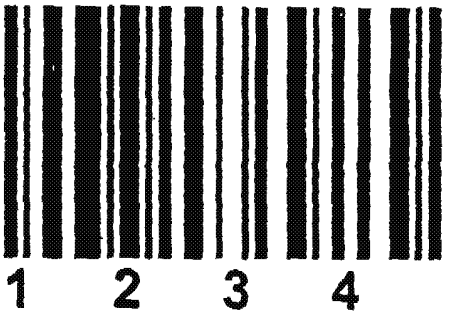
R. H. Lorenz (Signature) — October 23, 1970 (Date)

Vice President for Business and Finance
(Title)

SECTION

4

FINAL PROPOSAL



Building Capacity to Promote Pain Policy Through Evaluation, Research and Communication

A proposal to the Robert Wood Johnson Foundation

June 23, 1999

Submitted by

David E. Joranson, MSSW
Senior Scientist, Director
Pain & Policy Studies Group
University of Wisconsin Comprehensive Cancer Center
Madison WI

Table of Contents

Building Capacity to Promote Pain Policy Through Evaluation, Research and Communication

STATEMENT OF THE PROBLEM

In the last several years there has been a surge of national interest in state health policies affecting end-of-life care, including policies that influence pain management. Building on an existing movement in legislatures and state medical boards to clarify the role of controlled substances in pain management, the new trend is much broader and is being driven by an increasing number of influential groups that are working to improve end-of-life policy, practice, and palliative care. Many of these groups, representing patients, government, and a range of health care interests, are targeting state regulatory policies for change because they understand that adequate pain management is one essential part of quality end-of-life care. These groups include the Institute of Medicine, the American Medical Association, state medical and pharmacy associations, state government task forces and commissions, hospice organizations, the Community-State Partnerships to Improve End-of-Life-Care, Americans for Better Care of the Dying, state cancer pain initiatives, and state medical boards.

While the potential for such groups to make change is great, each group would need to 'invent the wheel' in order to systematically identify problems in their states' policies in order to be thorough. The development of alternatives may result in a wild variety of policies that do not take advantage of valid medical and legal principles and experience with policy development in this important area. The potential for these groups to improve pain management policy will be enhanced if they have access to policy resources that can help them to understand, evaluate, and improve pain policy. For example, our recent content evaluation of state medical board guidelines employed recognized medical and legal principles, and resulted in the development of a new and progressive "Model Guidelines for Use of Controlled Substances in Pain Management" (FSMB, May, 1998). These model guidelines, if adopted by state medical boards, could establish a more consistent national policy to improve pain management and address physician concern about being investigated when prescribing controlled substances.

At present, however, a set of principles for evaluating pain policy is lacking, as is a state-by- state evaluation of regulatory impediments. In addition, all state pain policies should be more easily accessible, with updates on the progress and issues as policies change from year to year. Surveys would provide valuable information about how physicians and regulators perceive changes in pain policies. Finally, these resources should be communicated to key audiences quickly and efficiently.

The Pain & Policy Studies Group (PPSG) has piloted the development of tools for this task, and would like to accomplish the work and make available the results to the groups who can contribute to improving state pain related policy.

BROAD PURPOSE

There is a window of opportunity now, while the interest in pain relief and palliative care is high and still growing. Therefore, we propose to accomplish a systematic and comprehensive state-by-state evaluation of impediments in pain-related policies, communicate the results to interested groups in ways that will increase their capability to understand, evaluate and make positive changes; we will also study the effects of policy changes. The grant will accomplish this objective through three interrelated parts: (1) policy evaluation, (2) research, and (3) communications.

ADVISORS TO THE PROJECT

A multidisciplinary group of advisors will be appointed to assist the project staff in several key phases of the grant, including in the preparation and application of criteria for the policy evaluation, reviewing products in draft form prior to dissemination, and advising us on effective communication strategies. We will obtain additional input from others as needed, including specialized assistance from consultants (see Consultants section under Budget narrative). The advisors are professionals who are health or legal experts and who have made significant contributions to medical and legal policy in the area of cancer and non-cancer pain management. We will have regular communication with the advisors over the course of the grant – there will be periodic teleconferences with the advisors according to their availability. Individual meetings may be accomplished at national conferences of groups such as the American Pain Society. The following individuals have agreed to be advisors; others may be added as needed.

1. June L. Dahl, Ph.D.: Dr. Dahl is a pain management pharmacologist and leads the national Cancer Pain Initiative movement. She has lectured extensively to health-care professionals about the pharmacological management of pain and about barriers to effective pain management. She is currently working to make pain management a priority in the health-care system and will be able to represent the needs of state cancer pain initiatives in relation to regulatory issues.

2. Russell R. Portenoy, M.D.: Dr. Portenoy has published and spoken frequently on the appropriate use of opioids for chronic cancer and non-cancer pain in relation to the regulatory climate, has worked with state medical boards, and is knowledgeable about the regulatory situation in a key state, New York.

3. Betty Ferrell, R.N., Ph.D.: Dr. Ferrell has published and spoken widely on the impact of pain on the patient, addressing regulatory barriers to pain management, and improving pain management nursing practice and education. In her capacity as chair of the Southern California Cancer Pain Initiative, she is familiar with regulatory issues in relation to patient care, particularly in another key state, California.

4. J. David Haddox, D.D.S., M.D.: Dr. Haddox is the current President of the American

Academy of Pain Medicine and a former Director of the American Pain Society. He is certified in general psychiatry and addiction psychiatry by the American Board of Psychiatry and Neurology and is certified by the American Board of Pain Medicine, of which he is a past President. He lectures frequently on topics in pain medicine, has served as faculty for eleven workshops for state medical board members and has a special interest in regulatory and policy aspects of the practice of pain medicine.

5. Myra Christopher, B.A.: Myra Christopher is Director of the Midwest Bioethics Center and its National Program Office for the Robert Wood Johnson Foundation, Inc. She has special knowledge of palliative care ethics and public policy, as well as an understanding of the needs of the new Community-State Partnerships to Improve End-of-Life-Care.

6. James Winn, M.D.: Dr. Winn is Executive Vice President of the Federation of State Medical Boards of the United States (FSMB), is a former member of the Alabama Board of Medical Examiners, and has a broad knowledge of the regulatory aspects of medical practice. Under his guidance, the Federation has approved and recommended to the state medical boards a "Model Guideline for the Use of Controlled Substances in the Treatment of Pain."

7. Ronald Buzzeo, R.Ph.: Mr. Buzzeo is a pharmacist and former official of the United States Drug Enforcement Administration. He has a thorough knowledge of national controlled substances regulation from a law enforcement and regulatory perspective.

TIMELINE

A schedule for accomplishing the projects in this proposal is included in the Timeline section.

PRIMARY AIM

Building Capacity to Improve Pain Policy

Part 1. Policy evaluation

Five outcomes are proposed.

Products

(1) Guide to Evaluation of Federal and State Policies.[1] Year 1: A document will be developed

[1] Policies to be evaluated include both *pain-related* and *pain-specific* policies. *Pain-related* policies include laws, regulations, or guidelines that have the potential to affect pain management although they may not

that contains a state-by-state presentation of specific regulatory provisions that we will identify in a major criteria-based evaluation of federal and state medical, pharmacy and controlled substances laws and regulations (as of 1998) as having the potential to impede pain management, as well as provisions which can be considered as preferable alternatives.

(2) Changes in Federal and State Policy: 1998-2001. Year 3: A report will be developed to describe the changes that have occurred in the two years since the Year 1 Guide, above.

(3) Annual Review of New State Pain Policies. Years 1, 2, 3: Three separate summaries of the pain-specific policies adopted in the previous year will be created and disseminated.

(4) Electronic Access to State Pain Policies. Years 1, 2, 3: Our present compilation of state pain policies will be continuously updated and be formatted in a matrix-driven database containing the complete language of all pain-specific policies in state laws, regulations and guidelines.

(5) Evaluations of Medical Board Pain Guidelines. Years 2, 3: Two additional policy evaluations will be conducted, one comparing the quality of the medical board pain guidelines adopted before the publication of the FSMB Model Guideline in 1998, with those adopted in the next two years; and one comparing this latter group with the Model Guideline.

Procedures

Data collection: Policy data will be collected primarily through the use of LEXIS, an up-to-date searchable computerized legal data-base for all federal and state laws and many state regulations.[2] Administrative policies related to pain that are not available from LEXIS, such as administrative codes and medical and pharmacy board guidelines, will be obtained directly from the state agencies.[3]

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specifically mention pain, such as a state's use of special prescription forms, dosage unit limitations, and definitions of "addiction" that may contribute to confusion between an "addict" and a legitimate pain patient. *Pain-specific* policies include laws, regulations, or guidelines that directly address the use of controlled substances for pain management, primarily laws such as Intractable Pain Treatment Acts [IPTAs], or administrative regulations and medical board guidelines relating to prescribing opioid analgesics for pain. For the purpose of this grant, pain-related policies can include pain-specific policies.

[2] We have chosen not to use the National Conference of State Legislatures (NCSL) Health Policy Tracking Service, which monitors health-care bills introduced and adopted by state legislatures, because this service does not make available the actual text of the policies but rather only summaries of each legislative bill.

[3] We have state agency mailing lists and will send periodic requests. Our experience in requesting public policies indicates that this is an effective method to obtain state administrative policies.

(1) Guide to Evaluation of Federal and State Policies. The "Guide to Evaluation of State Policies" will be a document designed as a workbook to assist people and groups who want to learn how to evaluate policies that can affect pain management in their state; it will explain the policy evaluation process, present a set of well-documented criteria for evaluating policy, list the provisions that were identified by our own application of the criteria to the policies of each state as of December 31, 1998, and offer model provisions that can be considered as alternatives. The Guide itself will be a reasonable number of pages of summarized information, which will include a matrix, or guide, to the provisions found in each state and at the federal level. Two Appendices will be available separately which will contain the exact language of provisions and alternatives for those who want a greater level of detail. The Guide will also contain an overview of pain-related policy and a glossary of terminology, so that it will be useful not only for the experienced policy analyst but also to those who are new to policy evaluation.

The Guide will be prepared in a hard-copy format, and placed on the PPSG website as soon as possible but before the end of the first year. The Guide will be disseminated to all Robert Wood Johnson Foundation-supported Community-State Partnerships, other grantees including Last Acts, and to State Cancer Pain Initiatives, State Medical Societies and many other organizations.

The tentative outline of the Guide is as follows:

Section I: Introduction: This section will explain the nature of policy analysis and pain policy, as well as the relationship of pain policy to medical practice and to patient care.

Section II: Principles, Criteria and Questions: This section will present the international and national principles that will be used to develop the criteria and questions that will be used to evaluate both federal and state pain policies. This section will draw on (a) a review of the literature[4], (b) our previous work to identify established legal and medical principles (Joranson, 1990; Joranson & Gilson, 1994a, 1994b) and (c) a document which is in preparation for the World Health Organization titled "Guidelines for Evaluating National Narcotic Control Policies for Balance."

The evaluation is a process that involves three steps:

(1) outline principles,
(2) convert principles to criteria and questions
(3) evaluate policies according to the criteria and questions.

The first step is a presentation of the principles. For example, one of the most important

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[4] e.g., the federal Controlled Substances Act and its legislative history (1970), the Clinical Practice Guidelines of the Agency for Health Care Policy and Research (Acute Pain Management Guideline Panel, February, 1992; Jacox et al., March, 1994), the Single Convention on Narcotic Drugs (United Nations, 1961), and Cancer Pain Relief with a Guide to Opioid Availability (World Health Organization, 1996).

principles is that drug control laws should contain certain positive declarations that recognize that controlled substances, in addition to posing a potential threat to public health, are also necessary to maintain public health, and that the use of controlled substances to relieve pain is a legitimate medical practice.

In the second step, the principles will be converted into evaluation criteria, and expressed as questions on a checklist that will guide the user through the third step, which is to evaluate the law, regulation or other policy for the presence or absence of provisions.

The following is an example of the first two steps, beginning with a different principle, and then deriving the criterion that is then expressed as a question:

> The principle is that physicians, rather than government, should make decisions about how patients' medical conditions should be treated so that they are based on the physician's expertise and the patient's needs; a resulting evaluation criterion would be to look for "any state policies that restrict physician decisions regarding amount or duration of drug treatment;" the question derived from the criterion would be "Does this state have any policies that restrict the quantity of a controlled substance that can be prescribed?"

Using the criteria, we will identify provisions as "identified provisions"(i.e., those provisions in federal and state public policy that are either consistent or inconsistent with the established criteria) that correspond to either of the following two requirements:

(1) (Should be present) Provisions that can positively affect pain management, i.e., a state controlled substances policy that recognizes that the medical use of controlled substances for intractable pain is a legitimate medical practice; or

(2) (Should not be present) Provisions that can negatively affect pain management, i.e., a state regulation that restricts the number of dosage units of controlled drugs that can be prescribed at one time for a patient.

Section III: (Results) Presentation of provisions identified by the evaluation: The scope of the evaluation will include federal policies, as well as all medical, pharmacy and controlled substances laws, regulations and other policies, such as guidelines, for every state. This could amount to as many as nine different policies evaluated for each state. The approximate number of public policies to be collected and evaluated are described in Table 1.

Table 1. Scope of Public Policy

	Controlled Substances	Medical Practice	Pharmacy Practice	Total
FEDERAL				

Laws	1	—	—	1
Regulations	1	—	—	1
STATE				
Laws	51	51	51	153
Regulations	25	51	51	127
Administrative Policies	—	25	5	30
Total	78	127	107	312

Table 2 is a greatly abbreviated matrix which will be used to present the provisions that we identify in the evaluation. A dot in a cell indicates that the PPSG evaluation found, according to the criteria, a particular provision in the policies of that state. Using this matrix, the user can quickly get an overview of the relevant provisions in their state.

Table 2. Identified Provisions matrix

	Positive provisions		**Negative provisions**
	Provision recognizing necessity of controlled substances for public health	**Provision recognizing as legitimate medical practice the medical use of controlled substances for pain**	**Quantity of Prescription is Restricted**
Alabama			
Alaska		•	
California		•	
Delaware			•
Texas		•	
Wisconsin	•	•	•

Section IV: Summary of identified provisions: This section will contain a state-by-state listing of all the provisions identified during the evaluation (including federal policies). This part of the Guide will enable the user to learn the type of provisions that were found, without having to go to the actual policies. An example of how this state-by-state synopsis will look can be found in Figure 1.

Figure 1. Summaries of Provisions

Alabama

o Inappropriate or inaccurate definition of pain-related terminology ("Intractable pain") (*Board of Medical Examiners, Physician's Guide to Controlled Substances Regulation §1306.07(c)*)

Arizona

o Inappropriate or inaccurate definition of addiction-related terminology ("drug dependent person") (*UCSA, Article 1, §36-2501 (A,5)*)

California

o Inappropriate or inaccurate definition of pain-related terminology ("Intractable pain") (*Medical Practice Act, Business and Professions Code, §2241.5 (b)*)

o Restricts patient access to pain management (prohibits prescribing or dispensing controlled substances to addicts or habitual users) (*UCSA, Chapter 4, Article 1, §11156 & Pharmacy Law, Chapter 9, Division 2, Article 7, §4362*)

o Restricts patient access to pain management (Requirement of special government prescription form for Schedule II opioid analgesics) (*UCSA, Chapter 4, Article 1, §11161*)

o Inappropriate or inaccurate definition of addiction-related terminology ("narcotic addict") (*Welfare and Institutions Code, Division 3, Chapter 1, Article 1, §3009*)

Users of the Guide will benefit from knowing the legislative history of identified provisions. For example, knowing that the historical origin of provisions that limit the prescription of "narcotics" predates today's knowledge about opioid analgesics will help to explain the need to revise and update policy. Therefore, Section IV will present a discussion of the background or history of selected "identified impediments". This part will present the results of our legal research to explain the original intent of the language in the context of prevailing attitudes about opioids. For example, the term "addict" began to appear in state laws well before the 1970's when experts believed that mere exposure to narcotics like morphine was the major factor in producing addiction, diagnosed solely by the presence of physical dependence. Examples of other provisions that our legal consultant will research are the origins of required reporting of addicts, the definition of "intractable pain" which places use of opioids for chronic pain outside of generally accepted medical practice, and the requirement for consultation as a condition of treatment. This section will discuss whether removing such impediments are likely to increase the abuse of opioid analgesics, or whether removal will simply reduce the impediments to pain management.

Section V: Models for change: This section will list summaries of provisions that can be used to improve state pain policies or serve as alternative language to provisions that are impediments.

These provisions will be drawn from some of the same sources as the principles and will be consistent with the criteria. For example, we will draw from the Model Uniform Controlled Substances Acts (National Conference of Commissioners on Uniform State Laws, August, 1970; July, 1990), the federal Controlled Substances Act (CSA, 1970), Model Guidelines for the Use of Controlled Substances in the Treatment of Pain (FSMB, May, 1998), as well as provisions adopted (or repealed) by states to redress impediments such as replacing triplicate prescription programs with electronic prescription monitoring programs, or the repeal of dosage limitations.

Thus, in addition to learning how to evaluate policy using criteria, and in addition to seeing the results of such an evaluation, users of Guide will have examples of policy alternatives including changes that have occurred in states to address impediments. The availability of alternatives may facilitate the change process, since it eliminates time-consuming steps that might not otherwise be taken to learn what options are available. An example of how Section V would be formatted, according to each identified provision, is provided in Figure 2.

Figure 2. Alternative Provisions

Inaccurate/inappropriate definition of terms relating to addiction

1. New York State law until recently had legal definitions of "addiction" and "habitual user" which had the potential to include pain patients who are physically dependent on opioid analgesics. The state legislature revised both definitions to exclude pain patients, which became effective on November 1, 1998. (New York Public Health, Article 33, §3302)

2.

Quantity of prescription restricted-dosage amount

1. In Wisconsin, the Controlled Substances Board found that the '120 dosage units or 34 day supply' regulation of the Pharmacy Examining Board led to confusion and unnecessarily limited the prescribing of controlled substances, especially in the treatment of cancer pain. The Pharmacy Examining Board amended the regulation to repeal the 120 dosage unit restriction, while retaining the 34 day supply limitation. (Wisconsin Administrative Code, Pharmacy, §8.05)

2.

Section VI: Terms and concepts: This section will contain the definitions of commonly used medical and legal terms, as well as an overview of the federal and state regulatory system that affects the use of controlled substances for pain management.

Section VII: Appendices: To reduce the size and complexity of the Guide, two separately available Appendices will contain even more complete information about the provisions present in federal and state policy, which will be useful to a select group of individuals. The Appendices will be distributed to a more limited audience but will remain available to others by request.

Appendix A: Detail of Provisions from Section III, which will contain the full text and citations of the provisions identified by the criteria evaluation.

Appendix B: Alternative Provisions from Section V, which will contain the full text and citations of alternative policies that could be used to improve state pain policies.

Format and distribution. The "Guide to Evaluation of State Pain Policies" and the two Appendices will be put on the PPSG website. The matrix in Section III will be automated so that clicking on a dot in a cell will link the user directly to a down-loadable electronic document with the full text and citation of the provision, which in turn will be linked to the alternative provisions. This format will allow a user to move quickly through an extensive text database, identifying the impediments in any state, as well as alternative provisions. Such immediate access to complete pain policy information will give users the information necessary to identify impediments and craft alternatives that can be used to support changes in policy to improve pain management.

In addition to being available on the PPSG website, the Guide, its computerized matrix, and the two Appendices will be put on CD-ROM in a variety of formats for distribution to organizations or individuals who want local computer access to the information or may not have ready access to the Internet.

(2) Changes in Federal and State Policy: 1998-2001. In the last year of the grant, we will issue a report on all changes in pain policy that occurred in the three years since 1998. The document will summarize the status of policy impediments in 2001, compare it to the status in 1998, and provide a state-by-state review of the changes during the period. In addition, this report will analyze the trends and discuss future directions. This document will be useful for groups with a long-term interest in improving pain policy in their state or at the federal level.

Format and distribution. This document will be provided in hard-copy format and will be available on the PPSG website. Distribution will be to the list of organizations who received the Guide, plus the groups who become involved in pain policy during the next few years.

(3) Annual Review of New State Pain Policies. In each year of the grant, a document will be prepared that summarizes all new or modified pain policies from the previous year, such as the adoption of intractable pain treatment acts and medical board regulations and guidelines on prescribing controlled substances for pain. The Annual Reviews will contain (a) the cumulative trend of pain policies since 1980, and (b) a state-by-state listing, citation, summary and commentary for each new policy in the previous year.

Format and distribution. The Annual Reviews will be made available on our website and will be distributed to key individuals and organizations such as health care providers, patient advocacy groups, state cancer pain initiatives, state government pain commissions, state pain summit meetings and task forces, state legislatures and medical boards.

(4) Compilation of State Pain Policies. The PPSG has received many positive comments about its down-loadable website database of the full text of pain policies currently in force, including relevant federal and state laws, regulations and guidelines. Therefore, this policy database will be continuously updated during the grant period. In addition, it will be upgraded to a more user-friendly menu-driven matrix format as in Table 2. Clicking on the dot in a cell will provide direct electronic access to the full text and citation of the pain policy. The accuracy and completeness of the Compilation data-base will continue to be assured through our internal quality control procedures and our regular monitoring of the policy environment.

Table 2. Matrix of State Pain Policies

	Laws	Regulations	Guidelines/Statements
Alabama		•	
Alaska			•
California	•		•
Delaware			
Texas	•	•	•
Wisconsin	•		

Format and distribution. The Compilation will continue to be available on the website, a CD-ROM with multiple file formats, and a limited number of hard copies will also be printed.

(5) Evaluations of Medical Board Guidelines. The adoption in 1998 of the FSMB "Model Guidelines for the Use of Controlled Substances for the Treatment of Pain" is an important event in the history of policy to improve pain management and to address physicians' fears of being investigated when prescribing opioids for patients with pain. We have already shown that the Model Guideline has a number of attributes that are lacking in the 24 guidelines which existed at the time the Model Guideline was adopted (Monterroso, Gilson, Williams, Nelson, & Joranson, November, 1998). For example, the FSMB encourages all licensed physicians to view pain management using controlled substances as a part of quality medical practice. Terms related to addiction and pain management are defined and used correctly, and for the first time, a clear and reasonable policy is established for the medical use of opioid analgesics to address physicians' fears of regulatory scrutiny.

Two evaluations using the Model Guideline will be accomplished. The first (in year 2) will compare the 24 medical board policies in 1998 with "second generation" policies, i.e., those that are adopted in the next two years; the second (in year 3) will compare the "second generation" policies with the parent policy, i.e., the Model Guideline. We hypothesize that policies developed after the Model Guideline was disseminated will reflect a higher quality of policy, i.e., they will contain language which is balanced in recognizing the medical use of

controlled substances, more direct in addressing physicians' concerns about investigation, and more accurate in terminology. These evaluations of the quality of guidelines will use the content analysis methodology (with modifications) that we used for the "Pain Management and State Regulatory Policy" grant (Joranson, 1997).

Part 2. Empirical research

Purpose

To complement the evaluation of pain policy, trends in abuse and medical utilization of opioid will continue to be studied in order to evaluate any changes in the rate of opioid analgesic abuse in the U.S.

Product

(1) Trends in abuse and medical utilization of opioids (1980-2000). Years 1, 2, 3: Analysis of the abuse of opioid analgesics compared to their medical consumption will be conducted to study changes in these important trends, which are indicators of the "balance" being achieved in preventing abuse while ensuring availability of opioids.

Procedures

(1) Trends in abuse and medical utilization of opioids (1980-2000). This section will contain several parts. The first part will be a report that updates the trends of abuse and medical use of opioid analgesics. In the previous grant we reviewed several data sets [2] and determined that from 1980-1995 the abuse of opioids such as morphine was very low and stable.[5] This was true despite large increases in medical use, according to consumption data supplied by the Drug Enforcement Administration (DEA). In this part, we will collect and study several more years of the Drug Abuse Warning Network (DAWN) and the Automated Records and Consolidated Orders System (ARCOS) data [3, 4]. We will also continue to receive reports from the Toxic Exposures Surveillance System (TESS) in an effort to corroborate the abuse trends with another source of morbidity data on opioid analgesics.

[5] Our preliminary comparison of the DAWN and ARCOS data, conducted during the first grant, revealed a consistently low abuse rate of Schedule II opioid analgesics, while the overall rate of drug abuse increased. In fact, the frequency of these drugs has declined as a percentage of all DAWN mentions by over 60% over the a 16-year study period, from 3.6% of all DAWN mentions in 1980 to 1.35% in 1995.

Part 3. Communications

Purpose

Consistent with the purpose of this grant, the purpose of this section is to increase awareness of pain policy issues and the ability of key individuals and organizations in government and health care to evaluate and improve policies that affect pain management. This will be accomplished by implementing a proactive outreach effort to communicate the products of this grant to a broader range of individuals and groups than we have had the capability for in the past. This goal will be accomplished using means in addition to ordinary channels of publishing articles and disseminating reports.

Products

Four outcomes are proposed.

(1) Maintenance of PPSG website. Years 1, 2, 3

(2) Expansion of PAINPOLICY listserve. Years 1, 2, 3

(3) Rapid and efficient technical assistance and dissemination of information. Years 1, 2, 3

Procedures

(1) Maintenance of PPSG website. The PPSG website is being used more and more, now averaging approximately 250 hits a day. At present, users can find information on our website about a range of pain policy issues, a compilation of current state policies, and resources in federal and state policy. We have received many positive comments: one prominent professional told us she uses the website extensively for research, another said he was a " real fan of the website." The website recently received an award from Growth House, Inc. for its content.[6] The use rates and comments suggest that the PPSG website has become a valuable policy resource that should be maintained.

We will expand the website to include the materials produced under the grant, including:

o "Guide to Evaluation of Federal and State Policies," linked electronically to appendices containing the full text of state pain-related policy provisions, and the full text of alternative language used by states to change policy,

o "Changes in Federal and State Policy: 1998-2001,"

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[6] Growth House, Inc. is an organization that deals with end-of-life issues.

o Three "Annual Review of New State Pain Policies"documents,

o Electronic access to State Pain Policies, including updated IPTAs, and medical board regulations and guidelines,[7] and

o Comprehensive links to other pain-related websites, as well as information about pain-related listserves such as Oncopain, Last Acts, Mayday Pain Link, Project on Death in America, and Midwest Bioethics Center and the Community-State Partnerships.

In addition, the website will be publicized through advertisements and notices in a variety of newsletters, professional journals, listserves, and e-mail broadcasts. Further, we will add resource materials produced by others with appropriate copyright permissions.

(2) Expansion of PAINPOLICY listserve. During the previous grant we piloted a listserve to provide a vehicle for multidisciplinary communication among individuals and groups who want to advance pain-related policy. The purposes (which do not include lobbying) are:

o discussion of pain-related regulatory and policy issues,

o discussion of whether a particular policy or proposal is a potential risk or benefit to pain management, and how to make such determinations,

o sharing of successful and unsuccessful approaches to overcoming policy barriers,

o sharing cases where patients or professionals have been affected positively or negatively by policy,

o disseminate news about changes in policy,

o announce meetings relevant to pain policy, and

o identify useful (or problematic) resource materials, journal articles, etc.

Recently, listserve discussions have included: (1) the FSMB's Model Guideline and how it is an improvement over existing state medical board guidelines, and (2) the recent trend in proposed state and federal policy which perpetuates the myth that use of opioids in pain management hastens death.

Current subscribers include representatives of the American Society of Pain Management

[7] The computerized matrix of state pain-specific policies will replace the "State Pain Policy Binder" developed during the first grant, although a hard-copy document will be made available for limited distribution to individuals without Internet access.

Nurses, the National Alliance for Breast Cancer, the Western Pain Society, the American Pain Foundation, the American Pharmaceutical Association, the American Academy of Pain Medicine, Hospice organizations, and state Cancer Pain Initiatives. Expansion of the listserve will include those from whom we have already received requests, as well as a much broader representation of individuals and groups.

(3) Technical assistance and dissemination of information. Staff time has been budgeted to respond to requests for assistance from an increasing number of health and government organizations including medical boards that are developing pain management and end-of-life Initiatives. These groups periodically request our review and comment on draft policies and typically incorporate our comments into the final policy. During the previous grant, such requests came from the National Foundation for the Treatment of Pain, the American Pain Foundation, the National Hospice Organization, the Institute of Medicine, the National Conference of State Legislatures, the American Pharmaceutical Association, the Arizona Board of Medical Examiners, the Maine Board of Medical Examiners, and the Federation of State Medical Boards.

Endnotes

[1] A national survey of practicing physicians was originally considered for this grant to increase the generalizability of results, but two substantial limitations argue against the use of such a methodology. First, because a primary aim of this survey is to gain an understanding of practitioner awareness of policy development in their state, there is a need to select some states in which policy creation or modification is being considered. The use of large-scale survey methodologies, such as Multi-Stage Probability Sampling or Probability-Proportionate-to-Size sampling, would not easily conform to this goal since the number of practitioners in each state (and not its policy environment) would determine the probability of a state's selection. Second, there is little need to make these surveys generalizable to every practitioner in the U.S. Our interest is specific to the changes in physicians' beliefs and attitudes over time as they become aware of policy activity in their state. It is highly doubtful that such policy change will occur in every state over the course of the grant period. There is, therefore, a need to select states based on their current or potential policy activity in order to maximize efficiency of the sampling process.

[2] The data-sets are: (1) Drug Abuse Warning Network (DAWN) Annual Emergency Department Data to identify substances associated with drug abuse episodes that are reported by a nationally-representative sample of emergency departments, (2) American Association of Poison Control Centers Toxic Exposure Surveillance System (TESS) Report, which tracks incidents of hazardous drug exposures reported to a large sample of poison control centers, (3) Substance Abuse and Mental Health Services Administration (SAMHSA) National Household Survey on Drug Abuse (NHSDA), which measures the overall prevalence of drug abuse in the U.S. by use of a stratified, multi-stage probability sample of households, and (4) Drug Enforcement Administration (DEA) Automated Records and Consolidated Orders System (ARCOS) , a federal computerized data system that collects data on the amounts of certain controlled substances that are distributed to the retail level, and which can be used to monitor the national and state patterns of "consumption," of certain controlled substances.

Evaluation of the NHSDA data-set during the first grant suggests that these data cannot be used effectively for our purposes because their standard reporting formats do not provide sufficiently detailed information about opioid analgesics such as morphine, oxycodone, and hydrocodone, while DAWN and ARCOS do. In addition, the availability of TESS data is compromised by the substantial cost associated with needing the American Association of Poison Control Centers to conduct data runs for the required drugs. As a result, we will collect only DAWN and ARCOS data for this grant.

[3] ARCOS is a national database that reports both national and state drug consumption for various controlled substances by both total grams consumed and grams/100,000 population. Through the use of ARCOS data, state drug consumption trends can be monitored to determine changes in opioid analgesic consumption over time. In fact, ARCOS data are used commonly by the DEA to rank states according to their retail distribution of a particular drug. Historically, states with high rankings were identified typically as "problem states" and efforts were begun to investigate possible reasons for such elevated consumption. In addition, a recent policy brief about Oregon used ARCOS data to quantify that Oregon currently ranks first among states for prescriptions of morphine — a statistic interpreted to reflect the "magnitude of Oregon's progress in pain

treatment for the dying" (State Initiatives in End-of-Life Care, June, 1998, p. 5).

[4] DAWN is a large-scale, ongoing retrospective survey of medical records that involves that collection of information from a multi-stage probability sampling of hospital Emergency Departments in 21 metropolitan and other non-metropolitan areas. Since 1990, the participating hospitals have constituted a representative sample of all such hospitals (SAMHSA, 1996; SAMHSA, 1991). DAWN is the most widely-cited national drug abuse monitoring system (Adams 1990, 1991; Adams & Kopstein 1993; Anthony 1979; Cooper et al 1992; DEA 1995; Eissenberg 1997; GAO 1978, 1982; Greenfield 1995; Haislip 1992; Hollister 1990; Jacob 1990; Lambert 1990; Office of Inspector General 1991) and is, therefore, familiar to drug abuse researchers.

References

Acute Pain Management Guideline Panel. (February, 1992). Acute pain management: Operative or medical procedures and trauma. AHCPR Publication No. 92-0032. Rockville, MD. Agency for Health Care Policy and Research, US Department of Health and Human Services, Public Health Service.

Adams, E.H. (1990). Interpreting the data on prescription drug abuse. In Wilford, B.B. (Ed.), *Balancing the response to prescription drug abuse* (pp. 19-24). Chicago, IL: American Medical Association.

Adams, E.H. (1991). Prevalence of prescription drug abuse: Data from the National Institute on Drug Abuse. *New York State Journal of Medicine, 91*(11), S32S-S36.

Adams, E.H., Kopstein, A.N. (1993). The nonmedical use of prescription drugs in the United States. In Cooper, J.R., Czechowicz, D.J., Molinari, S.P., Petersen, R.C. (Eds.), *Impact of prescription drug diversion control systems on medical practice and patient care* (pp. 109-119). Rockville, MD: National Institute on Drug Abuse Research Monograph 131.

American Academy of Pain Medicine and American Pain Society. (1997). *The use of opioids for the treatment of chronic pain.* A consensus statement from the American Academy of Pain Medicine and American Pain Society.

Anthony, J.C. (1979). The effect of federal drug law on the incidence of drug abuse. *Journal of Health, Politics, Policy and Law, 4*(1), 87-108.

Controlled Substances Act. (1970). Public Law No. 91-513, 84 Stat 1242.

Cooper, J.R., Czechowicz, D.J., Petersen, R.C., Molinari, S.P. (1992). Prescription drug diversion control and medical practice. *JAMA, 268*(10), 1306-1310.

Drug Enforcement Administration. (June, 1995). *Seventh pharmaceutical industry conference: Partnerships for action, new strategies for the future.* United States Department of Justice.

Eissenberg, T., Bigelow, G.E., Strain, E.C., et al. (1997). Dose-related efficacy of levormethadyl acetate for treatment of opioid dependence. *JAMA, 277*, 1945-1951.

Federation of State Medical Boards of the United States. (May, 1998). *Model guidelines for the use of controlled substances for the treatment of pain.* A policy document of the Federation of State Medical Boards of the United States, Inc.

General Accounting Office. (March 10, 1978). *Retail diversion of legal drugs - A major problem with no easy solution.*

General Accounting Office. (October 29, 1982). *Comprehensive approach needed to help control prescription drug abuse.*

Gilson, A.M., & Joranson, D.E. (October, 1997). *Second survey of state medical boards: Changes since 1991.* Poster presented at the 16th Annual Meeting of the American Pain Society, New Orleans, LA.

Greenfield, D.P. (1995). *Prescription drug abuse and dependence: How prescription drug abuse contributes to the drug abuse epidemic.* Springfield, IL: Charles C. Thomas Publisher.

Haislip, G.R. (July 29, 1992). *Statement to the Select Committee on Narcotics Abuse and Control: Pill mills, medicaid fraud, and the diversion of pharmaceuticals.* One hundred second Congress, second session. Washington, DC: U.S. Government Printing Office.

Hollister, A.S. (1990). Patterns of scheduled drug prescribing abuse by Tennessee physicians. *Substance Abuse, 11*(2), 69-78.

International Narcotics Control Board. (1996). *Report of the International Narcotics Control Board for 1995: Availability of opiates for medical needs.* Special report prepared pursuant to Economic and Social Council resolutions 1990/31 and 1991/43. United Nations, New York.

Jacob, T.R.. Multiple copy prescription regulation and drug abuse: Evidence from the DAWN network. In Wilford, B.B. (Ed.), *Balancing the response to prescription drug abuse* (pp. 205-216). Chicago, IL: American Medical Association.

Jacox, A., Carr, D.B., Payne, R., et al. (March, 1994). *Management of cancer pain: Clinical practice guideline No. 9.* AHCPR Publication No. 94-0592. Rockville, MD. Agency for Health Care Policy and Research, US Department of Health and Human Services, Public Health Service.

Joranson, D.E. (1990). Federal and state regulation of opioids. *Journal of Pain and Symptom Management, 5*, S12-S23.

Joranson, D.E. (February, 1997). *Pain management and state regulatory policy.* A grant to the Robert Wood Johnson Foundation.

Joranson, D.E. &Gilson, A.M. (1994a). Policy issues and imperatives in the use of opioids to treat pain in substance abusers. *Journal of Law, Medicine & Ethics, 22*(3), 5-13.

Joranson, D.E. & Gilson, A.M. (1994b). Controlled substances, medical practice, and the law. In Schwartz, H.I. (Ed.), *Psychiatric practice under fire: The influence of government, the media, and special interests on somatic therapies* (pp. 173-194). Washington, DC: American Psychiatric Press.

Joranson, D.E., Cleeland, C.S., Weissman, D.E., & Gilson, A.M. (1992). Opioids for chronic

cancer and non-cancer pain: A survey of state medical boards. *Federation Bulletin: The Journal of Medical Licensure and Discipline, 79*(4), 15-49.

Lambert, E.Y., & Schade, C.P. (1990). Assessment of prescription drug abuse in the United States. In Wilford, B.B. (Ed.), *Balancing the response to prescription drug abuse* (pp. 13-18). Chicago, IL: American Medical Association.

Monterroso, M., Gilson, A.M., Williams, C.M., Nelson, J.M., & Joranson, D.E. (November, 1998). *A comparison of state medical board pain guidelines with a national model.* Poster presented at the 17th Annual Meeting of the American Pain Society, San Diego, CA.

National Conference of Commissioners on Uniform State Laws. (August, 1970). *Uniform Controlled Substances Act.* St. Louis, MO.

National Conference of Commissioners on Uniform State Laws. (July, 1990). *Uniform Controlled Substances Act.* Milwaukee, WI.

Office of Inspector General. (1991). *Multiple Copy Prescription Programs: State experiences.* United States Department of Health and Human Services.

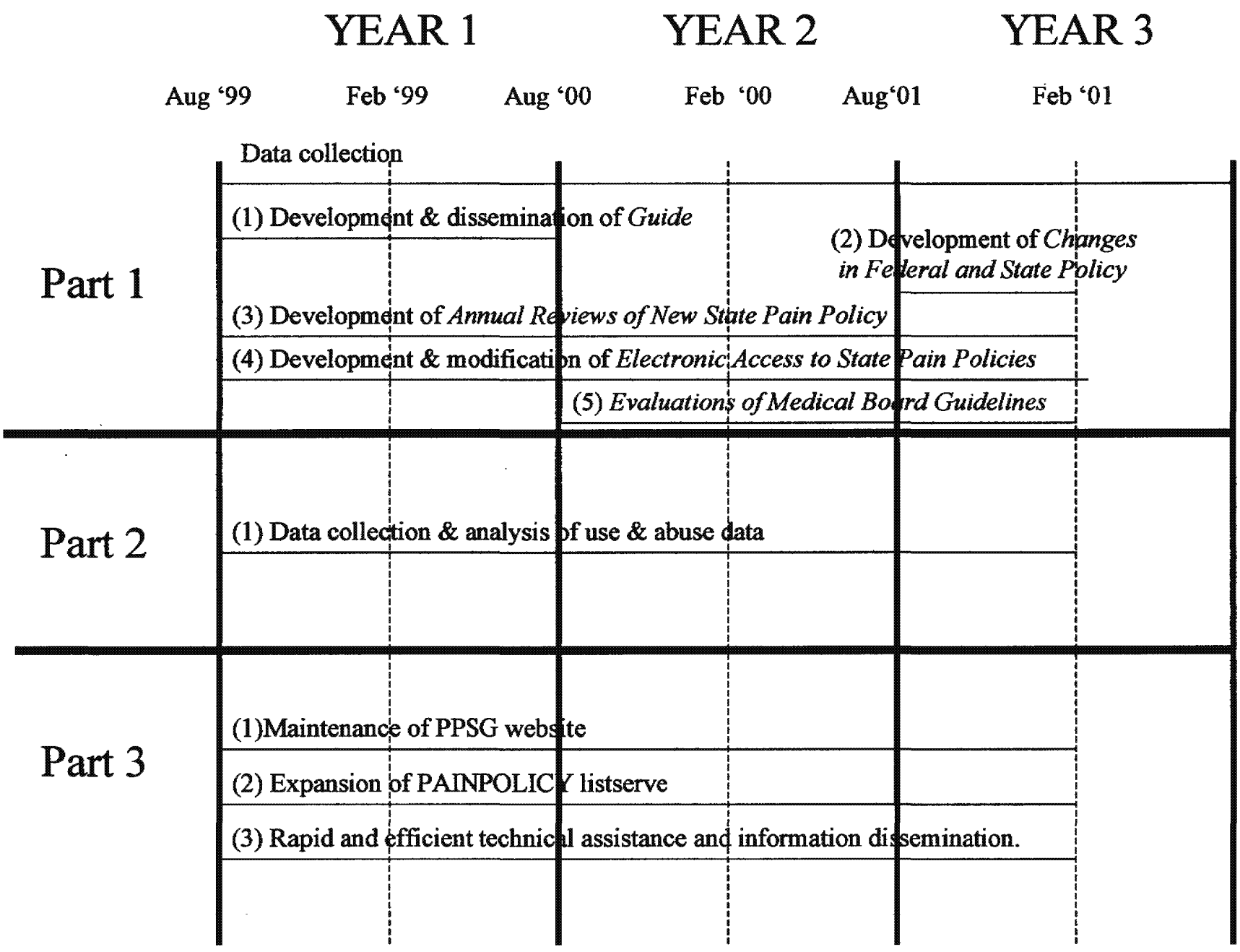
State Initiatives in End-of-Life Care. (June, 1998). *Focus on Oregon: Using qualitative and quantitative data to shape policy change.* A publication of the National Program for Community-State Partnerships to Improve End-of-Life Care in cooperation with the Last Acts Campaign.

Substance Abuse and Mental Health Administration. (1991). *Annual emergency room data, 1990: Data from the Drug Abuse Warning Network,* (Series I, Number 10-A). U.S. Department of Health and Human Services, Public Health Service. Rockville, MD.

Substance Abuse and Mental Health Administration. (October, 1996). *Annual emergency department data, 1994: Data from the Drug Abuse Warning Network,* (Series I, Number 14-A). U.S. Department of Health and Human Services, Public Health Service. Rockville, MD.

United Nations. (1961). *Single convention on narcotic drugs, 1961.* New York, NY.

World Health Organization. (1996). *Cancer pain relief with a guide to opioid availability.* Geneva, Switzerland.



36509

PAIN & POLICY STUDIES GROUP

WHO Collaborating Center
for Policy and Communications
in Cancer Care

THE ROBERT WOOD JOHNSON FOUNDATION

FEB 19 1999

ANSWERED | SCHEDULED | DATA ENTRY

February 17, 1999

Rosemary Gibson, Senior Program Officer
The Robert Wood Johnson Foundation
College Road East
P.O. Box 2316
Princeton, NJ 08543-2316

Re: Addendum

Dear Rosemary,

Further to our conference call on February 11, 1999, we are submitting this addendum to the grant proposal "Building Capacity to Promote Pain Policy Through Evaluation, Research and Communication." We will eliminate the proposed empirical studies and provide information you requested about other projects.

We proposed several surveys using repeat mailings and incentives of physicians and state regulators to study their perceptions of the unprecedented changes that are occurring in state laws, regulations and guidelines (in part due to our efforts). We have demonstrated that this type of methodology has provided statistically valid and reliable empirical data for studying the medical board member population. It may be possible as you suggest to increase the response rate for the third survey of all state medical board members in the U.S. from the 54% we received for our 1997 Time-2 mailed survey to the requested 80% return for our proposed Time-3 re-survey. We agree this is a desirable goal, but achieving this rate of return would necessitate a different and more expensive survey methodology that is not within the target budget. Therefore, this and other similar surveys are deleted from this proposal and budget: the surveys of medical board members, controlled substances regulators, physicians and pain specialists.

A question was raised about our proposed statistical study of the trends in abuse and medical use of opioids needed for severe pain. Due to the level of concern that increasing medical use of opioids in the class of morphine will lead to an increasing drug abuse problem, we proposed to conduct a statistically valid study that we hypothesized would confirm that abuse of opioids has been very low and stable over time for most opioids, compared to their rapidly increasing medical use. Due to the costs of acquiring the data needed for such an evaluation (according to our statistical consultant), we will eliminate this study. However, we wish to continue our study of the trends and of any year-to-year changes in the aggregate abuse and medical utilization of those opioid analgesics that are needed for managing severe pain, a trend that is especially relevant to public health policy in drug abuse and palliative care. The results of these latter studies will be communicated directly to professional audiences through publications,

UW Comprehensive Cancer Center - University of Wisconsin-Madison Medical School
1900 University Avenue Madison, WI 53705 USA (608) 263-7662 FAX: (608) 263-0259

conference presentations and periodic news updates.

Medical board guidelines--comparing the second generation to the first

Our content analysis of 24 medical board guidelines in 1997 resulted in the recognition that such guidelines were of variable quality, and also provided guidance for the development of a Model Guideline that state medical boards could follow. A question was raised about the purpose of the qualitative analysis we proposed to compare the first generation guidelines with later guidelines that had been developed with the benefit of a model policy. The purpose is to determine whether there are qualitative and quantitative differences (i.e., improvement) between the two periods, and thus to study whether a model guideline was an influence on subsequent policy. The results of this study will provide boards and their Federation with data that can be used to decide the next steps needed in achieving a uniform national policy to encourage better pain management and end of life care.

Technical assistance

The PPSG is regularly asked to provide comments on policies that are being developed related to pain management. A major example is the extensive assistance we provided to the National Conference of State Legislatures document on state legislation. In addition, we have responded to the following requests in the last three months:

1. (from the American Pain Foundation and the National Hospice Organization) for comments on draft federal legislation on pain management and end-of-life care authored by Ron Wyden (OR) titled "The Conquering Pain Act of 1999 " as a response to the "Lethal Drug Abuse Prevention Act,"

2. (from the American Medical Association (AMA) Council on Scientific Affairs) for comments on a draft report titled "Use of Opioids in Chronic Nonmalignant Pain,"

3. (from the Maine State Board of Registration in Medicine) for comments on a proposed state regulation titled "Use of Controlled Substances for Treatment of Pain,"

4. (from the Oklahoma State Cancer Pain Initiative) comments on a proposed state regulation Oklahoma State Board of Medical Licensure and Supervision titled "Intractable Pain Regulations,"

5. (from the Kansas State Cancer Pain Initiative) comments on draft state legislation relating to pain management introduced to the Legislature of the State of Kansas.

PPSG was asked to review these proposed policies to identify language or provisions that could lead to confusion or had the potential to create barriers to effective pain management. In fact, the review of the 20-page AMA draft report resulted in a six-page single-spaced letter that was submitted in short time to the Council on Scientific Affairs. The extensive amount of time and effort necessary to review the report and draft a response is the rule, rather than the

exception. Given the amount of time and effort to provide thoughtful and extensive comments regarding pain management policies, and with the likelihood that a greater number of future requests for review will be forthcoming given the increased number of pain-related policies being introduced, we believe that technical assistance is an important activity within the grant.

The total budget impact of these proposal modifications is contained in the adjusted Budget and Narrative section, enclosed with this letter.

Thank you for the opportunity to respond to your questions. We look forward to any further questions.

Sincerely,

David E. Joranson, M.S.S.W.
Senior Scientist, Director

Enclosure

36509

PAIN & POLICY STUDIES GROUP

WHO Collaborating Center
for Policy and Communications
in Cancer Care

THE ROBERT WOOD JOHNSON
FOUNDATION

JAN 28 1999

ANSWERED | RECORDED | DATA SHEET

January 26, 1999

Rosemary Gibson
Senior Program Officer
The Robert Wood Johnson Foundation
Route One and College Road East
Princeton, NY 08543-2316

See cover plus for final proposal.

Dear Ms. Gibson:

On behalf of the Pain & Policy Studies Group at the University of Wisconsin-Madison, we are requesting funding in the amount of ~~$1,823,391~~ $998,000. MH 7/29/99 for the project, *Building Capacity to Promote Pain Policy Through Evaluation, Research and Communication*, under the direction of David E. Joranson.

The attached copies of our tax documentation are true and correct copies of the originals on file with our institution and they remain in full force and effect.

The administrative officer of our organization is:

August Hackbart
Administrative Officer
University of Wisconsin System
750 University Avenue
Madison, WI 53706
(608) 262-0152

Sincerely,

David E. Joranson

David E. Joranson, MSSW
Senior Scientist, Director

August P. Hackbart

August Hackbart
Administrative Officer

Enclosures

32509

University of Wisconsin-Madison
Graduate School, Research and Sponsored Programs

THE ROBERT WOOD JOHNSON FOUNDATION

JAN 28 1999

ANSWERED	RECORDED	DATA SHEET

UW Proposal # 17587

The attached application has been administratively approved on behalf of the Board of Regents of the University of Wisconsin System and is submitted for your consideration. Please keep our office advised as developments occur with regard to this application.

We ask that you use the University's above-referenced proposal number in any future correspondence. Questions regarding administrative or contractual matters should be directed to Suzanne Samuelsen at (608) 262-6712. Questions regarding the technical nature of this application, should be directed to the Principal Investigator.

APPROVED:

August P. Hackbart 1-27-99

August P. Hackbart **Date**
Administrative Officer

400 A.W. Peterson Building
750 University Avenue
Madison, WI 53706-1490

Telephone (608) 262-3822
Fax (608) 262-5111
Home Page http://info.gradsch.wisc.edu/rsp/

SECTION

5

FINAL BUDGET & INTERIM BUDGET REPORTS

FINAL Budget
8/1/99 - 1/31/02 (30 MOS)
$998,000.
ID# 036509

THE ROBERT WOOD JOHNSON FOUNDATION
LINE ITEM BUDGET

Budget Period: (from 8/1/99 to 7/31/00)

PROJECT YEAR 1

I. PERSONNEL Name	Position	Base Salary	% Time	Total	RWJ Support	Other Support
David E. Joranson, MSSW	Project Director	$86,989	90%	$78,290	$78,290	
Aaron M. Gilson, PhD	Co-Director	$39,979	90%	$35,981	$35,981	
June L. Dahl, PhD	Project Advisor	$107,891	5%	$5,395	$5,395	
Karen M. Ryan, MA	Policy Analyst	$32,619	90%	$29,357	$29,357	
Carolyn M. Williams, MBA	Res. Program Manager	$45,325	75%	$33,994	$33,994	
John M. Nelson, MS	Info. Processing Consultant	$35,533	90%	$31,980	$31,980	
Martha A. Maurer, BS	Assoc. Research Spec.	$24,380	100%	$24,380	$24,380	
TBA	Outreach Specialist	$32,000	50%	$16,000	$16,000	
TBA	Program Assistant*	$21,231	50%	$10,615	$10,615	
TBA	Office Assistant**	$16,640	30%	$4,992	$4,992	
Fringe Benefits (34%, *42.5%, **3%)				$91,489	$91,489	
SUBTOTAL				$362,473	$362,473	
II. OTHER DIRECT COSTS						
OFFICE OPERATIONS						
Supplies				$2,700	$2,700	
Computer Supplies				$500	$500	
Duplicating/Printing				$2,865	$2,865	
Telephone				$2,155	$2,155	
Postage				$1,500	$1,500	
Service Agreements				$3,000	$3,000	
SOFTWARE				$6,500	$6,500	
TRAVEL				$15,960	$15,960	
SUBTOTAL				$35,180	$35,180	
III. INDIRECT COSTS (9%)				$35,789	$35,789	
IV. EQUIPMENT				$0	$0	
V. CONSULTANT/CONTRACTUAL AGREEMENTS				$44,000	$44,000	
TOTAL				$477,442	$477,442	

YEAR 1 $477,442.
YEAR 2 - 343,893.
YEAR 3 - 176,665
$998,000. mA 7/29/99

ACT 7/29/99

Budget Narrative
Grant Period: (from (8/1/99 to 1/31/02)
Budget Period: (from 8/1/99 to 7/31/00)

Project Year 1

I. PERSONNEL

Attached in Appendix A is a breakdown of percent effort per task as proposed in the three year project proposal.

Project Director, David E. Joranson, MSSW, 90% FTE
The project director is accountable for planning, organizing and directing the policy evaluation, research and communication programs of this project. Specific responsibilities include directing staff in designing a policy data collection protocol, overviewing the content analysis of laws, regulations and guidelines and reviewing reports and documents resulting from the policy evaluation. He will direct staff in the development of criteria and the analysis of results and will also direct the development of a communications network and the preparation of documents and reports that will be made available on the Website and in hardcopy to our target audiences.

Co-Director, Aaron M. Gilson, PhD, 90% FTE
The co-director will assist the director to plan, organize, and direct the projects in this proposal and will be responsible for conducting the content analysis of this project. He will also be responsible for the research design aspect of the policy evaluation program of this grant and will lead the work-group responsible for preparing the documents and reports resulting from the policy evaluation.

Project Advisor, June L. Dahl, PhD, 5% FTE
The project advisor of this proposal will be responsible for assisting project directors and staff in communicating and disseminating documents and reports to the target audiences. She will assist the project in responding to the needs of cancer pain initiatives and provide expertise in the area of pain management and pharmacology.

Policy Analyst, Karen M. Ryan, MA, 90% FTE
The policy analyst will be responsible for the content review of the laws, regulations and guidelines. These documents will be cataloged and reviewed for content and specific language that is defined by the presence or absence of positive and negative provisions. She will be involved with the conceptualization, formatting and creation of the annual reviews, evaluations and guidelines as outlined in the grant. She will prepare the trend analysis for opioid abuse and she will also serve as the moderator for the listserve.

Research Program Manager, Carolyn M. Williams, MBA, 75% FTE
The research program manager will assist the Co-Director in managing the day to day activities of this project including financial and personnel resources. She will assist the director and co-

director in distributing and coordinating work and will be responsible for estimating costs of programs, developing the budgets for each program activity, and preparing financial and progress reports. She will participate in research design, develop project timelines, and coordinate quality control of products.

Information Processing Consultant, John M. Nelson, MS, 90% FTE
The information processing consultant will oversee all data entry including the development and maintenance of a reference database which includes citations for publication and technical assistance. He will perform the data analysis for the evaluation of medical board guidelines. The information consultant will work with staff to develop the electronic matrix, and the linking of these and other supporting documents to the website and will assist in the maintenance of the Listserve. He will produce a CD-ROM version of the evaluation and supporting appendices.

Associate Research Specialist, Martha A. Maurer, BS, 100% FTE
The associate research specialist will be responsible for the monitoring, collection and organization of federal and state laws and regulations via Lexis, as well as working with state medical boards to obtain regulatory policies related to pain management. The associate research specialist will work with the directors and policy analyst to select appropriate policies, and convert them into computer-readable text documents. She will work with the information consultant to catalog the documents. She will be involved in the criteria-based evaluation of the collected policies and the medical board guideline evaluations. She will also assist in the preparation of documents and reports.

Outreach Specialist, TBA, 50% FTE
The outreach specialist will coordinate the efforts of the group to increase the awareness of pain policy issues and to broaden the dissemination of products of this proposal to key individuals and organizations in government and health care. This includes the evaluation guidelines, annual reports, and other documents. The outreach specialist will also assist the Associate Information Consultant in maintaining the website and assist in moderating the listserve to meet the needs of the many user groups. He/she will also work closely with the public relations firm to facilitate news bytes, releases, and briefings.

Program Assistant, TBA, 50% FTE
The program assistant will be responsible for responding to information requests and assisting staff members for production and dissemination of reports and documents to the target audiences of this proposal. He/she will support importing text. He/She will also provide organizational support and clerical support to other project staff on all projects. This is an hourly classified position thereby constituting a different fringe benefit rate than other project personnel.

Office Assistant, TBA, 30% FTE
The office assistant person(s) will assist in responding to information requests, and provide general office assistance such as filing, copying, and retrieval of library reference materials for the production and dissemination of the educational documents to be developed under this proposal. This position will be filled by undergraduate student workers.

FRINGE BENEFITS - Benefits are provided by the State of Wisconsin and administered by the University of Wisconsin System. A chart breaking down the components of the Fringe Benefit rates of University of Wisconsin employees is found in Figure 1.

Figure 1.

The Components of the fringe benefit rates for the University of Wisconsin

Benefit Category	Staff	Program Assistant	Office Assistant
Income Continuation	0.15	0.09	
Unemployment Comp.	0.16	0.17	
Worker's Comp.	0.32	0.33	
Social Security	5.71	6.07	1.91
Medicare	1.45	1.45	0.45
Health Insurance	11.79	19.37	
Life Insurance	0.07	0.10	
Retirement	14.20	14.20	
ERA Administration	0.01	0.01	
Prior Year Adj	0.14	0.71	0.64
Totals	34.00%	42.50%	3.00%

Title	Salary	Fringe Rate	Fringes
Project Director	$ 78,290	34.0%	$26,619
Co-Director	$ 35,981	34.0%	$12,234
Project Advisor	$ 5,395	34.0%	$ 1,834
Policy Analyst	$ 29,357	34.0%	$ 9,981
Res. Prog. Mgr.	$ 33,994	34.0%	$11,558
Info. Processing	$ 31,980	34.0%	$10,873
Assoc. Res. Spec.	$ 24,380	34.0%	$ 8,289
Outreach Spec.	$16,000	34.0%	$ 5,440
Program Assistant	$ 10,615	42.5.0%	$ 4,511
Office Assistant	$ 4,992	3.0%	$ 150
Total Fringes			$ 91,489

II OTHER DIRECT COSTS

Office Operations:

Supplies - The requested supply budget is $2,700 in Year 1. This includes $1,800 for office supplies such as fax paper, pens, pencils, file folders, and labels. Reference materials and the purchase of laws and regulations not available on the Internet is estimated at $900 per year. This is based on a collection of medical board regulations and nursing regulations done in 1996.

Computer supplies - We are requesting an estimated $500 for maintenance of computers.. This would include memory upgrades($120), hardware maintenance (i.e. cables, modems, hard drives(~$325)) , toner cartridges ($55), etc. These items will be purchased as needed.

Duplicating/printing - Costs for duplication of reference materials, reports and documents is $2,865. This is based on historical costs of similar reports that were prepared for a previous Robert Wood Johnson Foundation grant. All duplicating/printing is done by on-campus services or by UW or State contract, whatever is most economical.

Telephone - We are requesting support for ten telephone and modem lines for project personnel. Each person has two telephone lines (one dedicated modem line and one voice line). Yearly line rental per line is $175 for a total of $1,750. Line usage for telephone lines is estimated at $405. Total telephone charges of $2,155.

Postage - U.S. postage cost are estimated at $1,500. This includes the mailing of reports and correspondence, and the mailing of documents to target audiences. This cost is based on historical costs of similar mailings that were done for our previous Robert Wood Johnson Foundation grant and project for other funding sources.

Service Agreements - We will require service contracts for our copy machine and fax machine in order to maintain this equipment in proper condition. The yearly contract for the copy machine is $2,700 paid on a quarterly basis of $675 and the contract for one year service for our fax machine is $300. Our current Robert Wood Johnson Foundation grant (#031461) covered these costs during that project. We would like to request that these costs continue to be covered during this project period. It is important to our work to have these pieces of office equipment in good working order in order to be able to provide rapid and efficient technical assistance to other groups.

Software:

Software and database access is estimated at $6,500. The cost of subscribing to the Lexis online service, which provides access to law databases is $540 per month for a total cost of $6,500 per year.

7/29/99
PER CAROLYN WILLIAMS, HELP: Budgeted ALL 2-DAY TRIPS. MM

Travel:

The total cost of travel is estimated at $15,960. This comprises the cost of airline tickets, hotel and miscellaneous travel expenses for 14 trips ($1,140 each trip) for project staff. Project staff will attend various scientific meetings and conferences to present research data and products of this proposal. These meetings may include the American Pain Society annual meeting, the Pain Management and Chemical Dependency meeting, the State Cancer Pain Initiative National meeting, and State Community Partnerships. They will also be available to provide technical assistance to initiatives and other professional groups and entities.

III. INDIRECT COSTS.

Indirect costs are calculated at a 9% rate of budget categories I and II for a total indirect cost of $35,180

IV. EQUIPMENT

None.

V. CONSULTANT/CONTRACTUAL AGREEMENTS

Advisors

The advisors to this project will use their expertise to assist project staff in the preparation and application of policy evaluation criteria and in reviewing product drafts prior to dissemination. We will have regular communication with the advisors over the course of the grant and each have agreed to provide a two day commitment to the project at $500 per day.

The advisors include Russell Portenoy, MD; Betty Ferrell, RN, PhD; Myra Christopher, (payment declined); James Winn, MD; Ronald Buzzeo, R.Ph; J. David Haddox, DDS, MD at $1,000 per advisor for a total of $5,000.

Mr. Bill Marcus, JD, has agreed to be a legal consultant to the project. He will provide assistance with historical basis of legislation, legal citations, and identification of legal provisions that will be converted in to policy evaluation criteria. He has agreed to provide 8 days of consultation at $500 for a total of $4,000.

Communications

Funds are allocated to contract with a communications firm such as Burness Communications to assist in the dissemination of information and products of this proposal. It was estimated by Victoria Weisfeld, Senior Communications Officer of the Robert Wood Johnson Foundations that over the two and a half year period that the grant

covers that our communications cost would be $85,000. This would include three press briefings at $15,000 each (total of $45,000) and four press releases at $10,000 each (total of $40,000). The total cost over the two and a half years would be $85,000. For budgeting purposes, $35,000 are charged to year one and year two and $15,000 is charged to year three. The contract for communications is not in place at this time. This is a cost estimate.

THE ROBERT WOOD JOHNSON FOUNDATION
LINE ITEM BUDGET

Budget Period: (from 8/1/00 to 7/31/01)

PROJECT YEAR 2

I. PERSONNEL Name	Position	Base Salary	% Time	Total	RWJ Support	Other Support
David E. Joranson, MSSW	Project Director	$92,208	50%	$46,104	$46,104	
Aaron M. Gilson, PhD	Co-Director	$42,378	50%	$21,189	$21,189	
June L. Dahl, PhD	Project Advisor	$114,365	5%	$5,718	$5,718	
Karen M. Ryan, MA	Policy Analyst	$34,577	50%	$17,288	$17,288	
Carolyn M. Williams, MBA	Res. Program Manager	$48,044	50%	$24,022	$24,022	
John M. Nelson, MS	Info. Processing Consultant	$37,665	50%	$18,833	$18,833	
Martha A. Maurer, BS	Assoc. Research Spec.	$25,843	50%	$12,921	$12,921	
TBA	Outreach Specialist	$33,920	50%	$16,960	$16,960	
TBA	Program Assistant*	$22,504	50%	$11,252	$11,252	
TBA	Office Assistant**	$17,638	30%	$5,292	$5,292	
Fringe Benefits (34%, *42.5%, **3%)				$60,372	$60,372	
SUBTOTAL				$239,981	$239,951	

II. OTHER DIRECT COSTS

OFFICE OPERATIONS		
Supplies	$2,700	$2,700
Computer Supplies	$500	$500
Duplicating/Printing	$2,865	$2,865
Telephone	$2,155	$2,155
Postage	$1,500	$1,500
Service Agreements	$3,000	$3,000
SOFTWARE	$6,500	$6,500
TRAVEL	$15,960	$15,960
SUBTOTAL	$35,180	$35,180
III. INDIRECT COSTS (9%)	$24,762	$24,762
IV. EQUIPMENT	$0	$0
V. CONSULTANT/CONTRACTUAL AGREEMENTS	$44,000	$44,000
TOTAL	[illegible]	[illegible]

nwk 7/29/99

Budget Narrative
Grant Period: (from 8/1/99 to 1/31/02)
Budget Period: (from 8/1/00 to 7/31/01)

Project Year 2

I. PERSONNEL

There are no changes in personnel for Year 2. Salaries are increased by 6%. The State of Wisconsin is undergoing its's biannual budget process during the summer of 1999. Included in the budget is a pay "catch-up" package for University of Wisconsin academic staff. This "catch-up" package is to increase base salaries to be competitive with peer institutions. At this time, the news reports indicate that the salary increase will fall somewhere between 5.2 % and 6.5% each year for the next two years. The administration of the University of Wisconsin has advised that grant budgets should use a 6% salary increase for salary calculations.

Project Director	David E. Joranson, MSSW	50% FTE
Co-Director	Aaron M. Gilson, PhD	50% FTE
Project Advisor	June L. Dahl, PhD	5% FTE
Policy Analyst	Karen M. Ryan, MA	50% FTE
Research Program Manager	Carolyn M. Williams, MBA	50% FTE
Info. Processing Consultant	John M. Nelson, MS	50% FTE
Associate Research Specialist	Martha A. Maurer, BS	50% FTE
Outreach Specialist	TBA	50% FTE
Program Assistant	TBA	50% FTE
Office Assistant	TBA	30% FTE

FRINGE BENEFITS - Benefits are provided by the State of Wisconsin and administered by the University of Wisconsin System and include income continuation insurance, unemployment compensation, worker's compensation, social security, health insurance, retirement, and ERA administration. (See Figure 1, pg 4)

Title	Salary	Fringe Rate	Fringes
Project Director	$ 55,325	34.0%	$ 15,675
Co-Director	$ 27,546	34.0%	$ 7,204
Project Advisor	$ 5,718	34.0%	$ 1,944
Policy Analyst	$ 22,475	34.0%	$ 5,878
Res. Prog. Mgr.	$ 24,022	34.0%	$ 8,168
Info. Processing	$ 22,599	34.0%	$ 6,403
Assoc. Res. Spec.	$ 12,921	34.0%	$ 4,393
Outreach Spec.	$17,978	34.0%	$ 5,766
Program Assistant	$ 11,927	42.5.0%	$ 4,782
Office Assistant	$ 5,292	3.0%	$ 159
		Total Fringes	$ 60,372

II OTHER DIRECT COSTS

Office Operations:

Supplies - The requested supply budget remains at $2,700 in Year 2.
Computer Supplies - The requested computer supply budget remains at $500.
Duplicating/printing - The requested duplicating/printing budget remains at $2,865 in Year 2.
Telephone - Total telephone remains at $2,155 in Year 2.
Postage - U.S. postage costs are estimated at $1,500.
Service Agreements - Service agreements are estimated at $3,000 for Year 2.

Software:

Software and database access is estimated at $6,500. The cost of subscribing to the Lexis online service, which provides access to law databases is $540 per month for an approximate cost of $6,500 per year.

7/29/99

Travel:

The total cost of travel is estimated at $15,960 for fourteen staff trips to present data and provide technical assistance. (2 DAY TRIP MM

III. INDIRECT COSTS.

Indirect costs are calculated at a 9% rate of budget categories I and II for a total indirect cost of $24,762.

IV. EQUIPMENT

No equipment is requested in Year 2.

V. CONSULTANT/CONTRACTUAL AGREEMENTS

Advisors
The advisors include Russell Portenoy, MD; Betty Ferrell, RN, PhD; Myra Christopher, (payment declined); James Winn, MD; Ronald Buzzeo, R.Ph; J. David Haddox, DDS, MD at $1,000 per advisor for a total of $5,000.

Mr. Bill Marcus, JD, has agreed to be a legal consultant to the project. He has agreed to provide 8 days of consultation at $500 for a total of $4,000.

Communications
It is estimated that $35,000 will be needed in year one to prepare press releases and one press briefing in year 2 as described in year 1 justification.

THE ROBERT WOOD JOHNSON FOUNDATION
LINE ITEM BUDGET

Budget Period: (from 8/1/01 to 1/31/02)

PROJECT YEAR 3

I. PERSONNEL Name	Position	Base Salary	% Time	Total	RWJ Support	Other Support
David E. Joranson, MSSW	Project Director	$97,741	50%	$24,435	$24,435	
Aaron M. Gilson, PhD	Co-Director	$44,920	50%	$11,230	$11,230	
June L. Dahl, PhD	Project Advisor	$121,226	5%	$3,031	$3,031	
Karen M. Ryan, MA	Policy Analyst	$36,651	50%	$9,163	$9,163	
Carolyn M. Williams, MBA	Res. Program Manager	$50,927	50%	$12,732	$12,732	
John M. Nelson, MS	Info. Processing Consultant	$39,925	50%	$9,981	$9,981	
Martha A. Maurer, BS	Assoc. Research Spec.	$27,393	50%	$6,848	$6,848	
TBA	Outreach Specialist	$35,955	50%	$8,989	$8,989	
TBA	Program Assistant*	$23,855	50%	$5,964	$5,964	
TBA (students)	Office Assistant**	$18,697	30%	$2,805	$2,805	
Fringe Benefits (34%, *42.5%, **3%)				$31,998	$31,998	
SUBTOTAL				$127,176	$127,176	
II. OTHER DIRECT COSTS						
OFFICE OPERATIONS						
Supplies				$933	$933	
Computer Supplies				$250	$250	
Duplicating/Printing				$2,864	$2,864	
Telephone				$1,077	$1,077	
Postage				$750	$750	
Service Agreements				$1,500	$1,500	
SOFTWARE				$3,250	$3,250	
TRAVEL				$5,700	$5,700	
SUBTOTAL				$16,324	$16,324	
III. INDIRECT COSTS (9%)				$12,915	$12,915	
IV. EQUIPMENT				$0	$0	
V. CONSULTANT/CONTRACTUAL AGREEMENTS				$20,250	$20,250	
TOTAL				$176,665	$176,665	

MAC 7/23/99

Budget Narrative
Grant Period: (from 8/1/99 to 1/31/02)
Budget Period: (from 8/1/01 to 1/31/02)

NOTE: YEAR THREE IS A SIX MONTH PERIOD

Project Year 3

I. PERSONNEL

There are no changes in personnel for Year 2. Salaries are increased by 6%. A justification for this increase is given in year 2.

Project Director	David E. Joranson, MSSW	50% FTE
Co-Director	Aaron M. Gilson, PhD	50% FTE
Project Advisor	June L. Dahl, PhD	5% FTE
Policy Analyst	Karen M. Ryan, MA	50% FTE
Research Program Manager	Carolyn M. Williams, MBA	50% FTE
Info Processing Consultant	John M. Nelson, MS	50% FTE
Associate Research Specialist	Martha A. Maurer, BS	50% FTE
Outreach Specialist	TBA	50% FTE
Program Assistant	TBA	50% FTE
Office Assistant	TBA	30% FTE

FRINGE BENEFITS - Benefits are provided by the State of Wisconsin and administered by the University of Wisconsin System and include income continuation insurance, unemployment compensation, worker's compensation, social security, health insurance, retirement, and ERA administration.

Title	Salary	Fringe Rate	Fringes
Project Director	$ 29,322	34.0%	$ 8,308
Co-Director	$ 13,476	34.0%	$ 3,818
Project Advisor	$ 3,031	34.0%	$ 1,031
Policy Analyst	$ 11,912	34.0%	$ 3,115
Res. Prog. Mgr.	$ 12,732	34.0%	$ 4,329
Info. Processing	$ 11,978	34.0%	$ 3,394
Assoc. Res. Spec.	$ 6,848	34.0%	$ 2,328
Outreach Spec.	$ 9,528	34.0%	$ 3,056
Program Assistant	$ 6,321	42.5%	$ 2,535
Office Assistant	$ 2,805	3.0%	$ 84
		Total Fringes	$ 31,998

II OTHER DIRECT COSTS

Office Operations:

Supplies - The requested supply budget is $933 in Year 3.
Computer Supplies - The requested computer supply budget is $250 in Year 3.
* *Duplicating/printing* - The requested duplicating/printing budget is $2,864 in Year 3.
Telephone - Total telephone remains at $1,077 in Year 3.
Postage - U.S. postage costs are estimated at $750.
Service Agreements - Service agreements are estimated at $1,500 for Year 3.

Software:

Software and database access is estimated at $3,250. The cost of subscribing to the Lexis online service, which provides access to law databases is $540 per month for a approximate cost of $3,250 for 6 months.

Travel:

The total cost of travel is estimated at $ 5,700 for five staff trips to present data and provide technical assistance. (2-DAY TRIPS) 7/29/99 MH

III. INDIRECT COSTS.

Indirect costs are calculated at a 9% rate of budget categories I and II for a total indirect cost of $16,324

IV. EQUIPMENT

No equipment is requested in Year 3.

V. CONSULTANT/CONTRACTUAL AGREEMENTS

Advisors
The advisors include Russell Portenoy, MD; Betty Ferrell, RN, PhD; Myra Christopher, (payment declined); James Winn, MD; Ronald Buzzeo, R.Ph; and J. David Haddox, DDS, MD at $500 per advisor for a total of $2,500.

Mr. Bill Marcus, JD, has agreed to be a legal consultant to the project. He has agreed to provide 5.5 days of consultation at $500 for a total of $2,750.

Communications
It is estimated that $15,000 will be needed in year one to prepare press releases as described in the justification for year 1.

* Budgeted Amt is same for YRS 1 through 3, even though YR3 has a duration of only 6 MOS. Per Carolyn Williams, this is to cover anticipated printing/ duplication costs related to the production & distribution of the final grant/fin'l reports during YR 3. MH 7/29/99

THE ROBERT WOOD JOHNSON FOUNDATION
LINE ITEM BUDGET

Budget Period: (from8/1/99 to1/31/02)

I. PERSONNEL Name	Position	Year 1 % Time	Year 1 Total	Year 2 % Time	Year 2 Total	Year 3 % Time	Year 3 Total
David E. Joranson, MSSW	Project Director	90%	$78,250	50%	$46,104	50%	$24,435
Aaron M. Gilson, PhD	Co-Director	90%	$35,981	50%	$21,189	50%	$11,230
June L. Dahl, PhD	Project Advisor	5%	$5,395	5%	$5,718	5%	$3,031
Karen M. Ryan, MA	Policy Analyst	90%	$29,357	50%	$17,288	50%	$9,163
Carolyn M. Williams, MBA	Res. Program Manager	75%	$33,994	50%	$24,022	50%	$12,732
John M. Nelson, MS	Info. Processing Consultant	90%	$31,980	50%	$18,833	50%	$9,981
Martha A. Maurer, BS	Assoc. Research Spec.	100%	$24,380	50%	$12,921	50%	$6,848
TBA	Outreach Specialist	50%	$16,000	50%	$16,960	50%	$8,989
TBA	Program Assistant*	50%	$10,615	50%	$11,252	50%	$5,964
TBA (students)	Office Assistant**	30%	$4,992	30%	$5,292	30%	$2,805
Fringe Benefits (34%, *42.5%, **3%)			$91,489		$60,372		$31,998
SUBTOTAL			$363,473		$239,981		$127,176
II. OTHER DIRECT COSTS							
OFFICE OPERATIONS							
Supplies			$2,700		$2,700		$933
Computer Supplies			$500		$500		$250
Duplicating/Printing			$2,865		$2,865		$2,864
Telephone			$2,155		$2,155		$1,077
Postage			$1,500		$1,500		$750
Service Agreements			$3,000		$3,000		$1,500
SOFTWARE			$6,500		$6,500		$3,250
TRAVEL			$15,960		$15,960		$5,700
SUBTOTAL			$35,180		$35,180		$16,324
III. INDIRECT COSTS (9%)			$35,789		$24,762		$12,915
IV. EQUIPMENT			$0		$0		$0
V. CONSULTANT/CONTRACTUAL AGREEMENTS			$44,000		$44,000		$20,250
TOTAL			$477,442		$343,893		$176,665
TOTAL PROJECT COST							$998,000

7/23/99

APPENDIX A - Percent Effort per Task

Guide to Evaluation of Federal and State Policies. Year 1: A document will be developed that contains a state-by-state presentation of specific regulatory provisions that we will identify in a major criteria-based evaluation of federal and state medical, pharmacy and controlled substances laws and regulations (as of 1998) as having the potential to impede pain management, as well as provisions which can be considered as preferable alternatives.

		Year 1	Year 2	Year 3
Director	Joranson	30%		
Co Director	Gilson	55%		
Advisor	Dahl			
Policy Analyst	Ryan	50%		
Res. Prog. Mgr.	Williams	25%		
Info. Processing	Nelson			
Assoc. Res. Spec	Maurer	65%		
Outreach Spec.	TBA			
Prog. Assistant	TBA	10%		
Office Assistant	TBA	10%		

Changes in Federal and State Policy: 1998-2001. Year 3: A report will be developed to describe the changes that have occurred in the two years since the Year 1 Guide.

		Year 1	Year 2	Year 3
Director	Joranson			5%
Co Director	Gilson			5%
Advisor	Dahl			
Policy Analyst	Ryan			5%
Res. Prog. Mgr.	Williams			5%
Info. Processing	Nelson			
Assoc. Res. Spec	Maurer			15%
Outreach Spec.	TBA			
Prog. Assistant	TBA			10%
Office Assistant	TBA			5%

Annual Review of New State Pain Policies. Years 1, 2, 3: Three separate summaries of the pain-specific policies adopted in the previous year will be created and disseminated.

		Year 1	Year 2	Year 3
Director	Joranson	10%	10%	10%
Co Director	Gilson	15%	15%	15%
Advisor	Dahl			
Policy Analyst	Ryan	5%	5%	5%
Res. Prog. Mgr.	Williams	10%	10%	10%
Info. Processing	Nelson			
Assoc. Res. Spec	Maurer	10%	15%	10%
Outreach Spec.	TBA			
Prog. Assistant	TBA	10%	10%	10%
Office Assistant	TBA			

Electronic Access to State Pain Policies. Years 1, 2, 3: Our present compilation of state pain policies will be continuously updated and be formatted in a matrix-driven database containing the complete language of all pain-specific policies in state laws, regulations and guidelines.

		Year 1	Year 2	Year 3
Director	Joranson	5%	2%	2%
Co Director	Gilson	5%	5%	
Advisor	Dahl			
Policy Analyst	Ryan	5%	5%	
Res. Prog. Mgr.	Williams	15%	15%	15%
Info. Processing	Nelson	50%	25%	25%
Assoc. Res. Spec	Maurer	10%	10%	5%
Outreach Spec.	TBA			
Prog. Assistant	TBA	10%	10%	10%
Office Assistant	TBA	10%	10%	10%

Evaluations of Medical Board Pain Guidelines. Years 2, 3: Two additional policy evaluations will be conducted, one comparing the quality of the medical board pain guidelines adopted before the publication of the FSMB Model Guideline in 1998, with those adopted in the next two years; and one comparing this latter group with the Model Guideline.

		Year 1	Year 2	Year 3
Director	Joranson		2%	2%
Co Director	Gilson		15%	15%
Advisor	Dahl			
Policy Analyst	Ryan		10%	10%
Res. Prog. Mgr.	Williams		5%	5%
Info. Processing	Nelson		5%	5%
Assoc. Res. Spec	Maurer		10%	10%
Outreach Spec.	TBA			
Prog. Assistant	TBA		10%	
Office Assistant	TBA		10%	5%

Trends in abuse and medical utilization of opioids (1980-2000). Years 1, 2, and 3: A report that updates the trends of abuse and medical use of opioid analgesics will be prepared. We will collect and study several more years of the Drug Abuse Warning Network (DAWN) and the Automated Records and Consolidated Orders System (ARCOS) data

		Year 1	Year 2	Year 3
Director	Joranson	5%	2%	2%
Co Director	Gilson			
Advisor	Dahl			
Policy Analyst	Ryan	5%	5%	5%
Res. Prog. Mgr	Williams			
Info. Processing	Nelson			
Assoc. Res. Spec	Maurer	5%	5%	5%
Outreach Spec.	TBA			
Prog. Assistant	TBA			
Office Assistant	TBA			

Maintenance of PPSG website. Years 1, 2, 3

		Year 1	Year 2	Year 3
Director	Joranson	5%	2%	2%
Co Director	Gilson			
Advisor	Dahl			
Policy Analyst	Ryan	5%	5%	5%
Res. Prog. Mgr.	Williams	10%	10%	10%
Info. Processing	Nelson	20%	10%	10%
Assoc. Res. Spec	Maurer			
Outreach Spec.	TBA	15%	15%	15%
Prog. Assistant	TBA			
Office Assistant	TBA	10%	10%	10%

Expansion of PAINPOLICY listserve. Years 1, 2, 3

		Year 1	Year 2	Year 3
Director	Joranson	5%	2%	2%
Co Director	Gilson			
Advisor	Dahl			
Policy Analyst	Ryan	15%	15%	15%
Res. Prog. Mgr.	Williams	5%		
Info. Processing	Nelson	10%	5%	5%
Assoc. Res. Spec	Maurer			
Outreach Spec.	TBA	10%	10%	10%
Prog. Assistant	TBA			
Office Assistant	TBA			

Rapid and efficient technical assistance and dissemination of information. Years 1, 2, 3

		Year 1	Year 2	Year 3
Director	Joranson	30%	30%	30%
Co Director	Gilson	15%	15%	15%
Advisor	Dahl	5%	5%	5%
Policy Analyst	Ryan	10%	10%	10%
Res. Prog. Mgr.	Williams	10%	10%	10%
Info. Processing	Nelson	10%	5%	5%
Assoc. Res. Spec	Maurer	10%	10%	10%
Outreach Spec.	TBA	25%	25%	25%
Prog. Assistant	TBA	20%	20%	20%
Office Assistant	TBA			

THE
ROBERT WOOD
JOHNSON
FOUNDATION

1/B
EOL

October 21, 2002

Robert C. Andresen
Administrative Officer
Research and Sponsored Programs
University of Wisconsin-Madison
750 University Avenue, 4th Floor
Madison, WI 53706-1490

Reference: I.D. #036509 - Budget Revision Received/Approved

Dear Mr. Andresen:

This is in reference to your Robert Wood Johnson Foundation grant in support of the Targeted End-of-Life Projects Initiative: a project to assess states' pain policies.

We have received your budget revision for the period of January 31, 2002, through April 30, 2002 and approved it. We will consider this submission as backup for your final financial report which reflected overexpenditures in the "Personnel" and "Other Direct" categories.

Please note, a letter of explanation for the overexpenditures in year 02 on the "Other Direct Subtotal" in our letter dated October 18, 2001, is currently outstanding. Once this letter of explanation is received we will release your final payment.

Cumulative expenditures as of April 30, 2002, have been $977,073. The Foundation has made payments to date totaling $761,573 leaving you a cash deficit as of April 30, 2002, of $215,500. Once the letter of explanation is received, we will release your final payment.

Office of the Vice President and Treasurer

Route 1 and College Road East Post Office Box 2316 Princeton, New Jersey 08543-2316 (609) 452-8701

If I can assist you further, please contact me at 609-627-5844.

Sincerely,

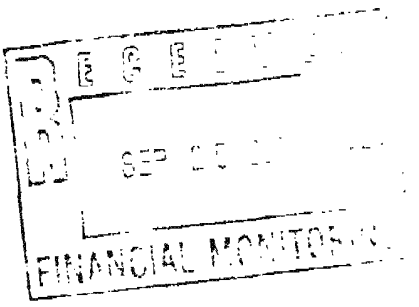
Sophia Kounelias
Financial Analyst

/SXK

cc: David E. Joranson, M.S.S.W.
Rosemary Gibson

PAIN & POLICY STUDIES GROUP

WHO Collaborating Center
for Policy and Communications
in Cancer Care



September 23, 2002

Sophia Kounelias, Financial Analyst
Robert Wood Johnson Foundation
Route 1 and College Road East
Post Office Box 2316
Princeton, NJ 08543-2316

Reference: RWJF # 036509, Building Capacity to Promote Pain Policy Through Evaluation, Research and Communication
UW # 133-CW36

Dear Ms. Kounelias:

I am writing to request approval of a rebudgeting for the above referenced grant. A request to extend the grant from January 31, 2002 through April 30, 2002 was approved in your letter dated April 29, 2002. The budget revisions are mainly to extend salaries for February through April 2002 and to revise other direct cost items to reflect actual expenditures. The revised budget and budget narrative are enclosed for your review.

I hope that this request meets with the approval of the Foundation.

Sincerely,

David Joranson

David Joranson
Senior Scientist and Director

Enclosures

Cc Comprehensive Cancer Center
Medical School

UW Comprehensive Cancer Center - University of Wisconsin-Madison Medical School
406 Science Drive, Suite 202 Madison, WI 53711-1068 USA (608) 263-7662 FAX: (608) 263-0259
www.medsch.wisc.edu/painpolicy

BUILDING CAPACITY TO PROMOTE PAIN POLICY THROUGH EVALUATION, RESEARCH AND COMMUNICATION

Principal Investigator: David E. Joranson
Robert Wood Johnson Foundation ID # 036509
UW- Madison 133-CW36

Grant Period: August 1, 1999 - April 30, 2002
Budget Period: August 1, 2001 - April 30, 2002

	Approved Amount	*Revision Request*	*Proposed Budget*	**Estimated Expenses Incurred through Apr-02**
I-Personnel				
Project Director	$24,435	$17,941	$42,376	$42,375.83
Co-Director	$11,230	$6,879	$18,109	$18,109.49
Project Advisor	$3,031	$65	$3,096	$3,095.62
Project Analyst	$9,163	$5,472	$14,635	$14,635.24
Research Program Manager	$12,732	$3,217	$15,949	$15,949.14
Information Processing Consultant	$9,981	($4,862)	$5,119	$5,119.29
Associate Research Specialist	$6,848	$4,613	$11,461	$11,460.74
Outreach Specialist	$8,989	$11	$9,000	$9,000.00
Program Assistant	$5,964	$6,430	$12,394	$12,393.50
Office Assistant	$2,805	$85	$2,890	$2,890.48
Subtotal Personnel	*$95,178*	*$39,851*	*$135,029*	*$135,029.33*
Fringes	*$31,998*	*$12,076*	*$44,074*	*$44,073.74*
Total Personnel	**$127,176**	**$51,927**	**$179,103**	**$179,103.07**
II-Other Direct Costs				
Supplies	$933	($7)	$926	$926.00
Computer Supplies	$250	$20	$270	$270.00
Duplicating/Printing	$2,864	($277)	$2,587	$2,586.54
Telephone	$1,077	$130	$1,207	$1,206.71
Postage	$750	$0	$750	$750.00
Service Agreements	$1,500	($784)	$716	$716.25
Software	$3,250	$2,690	$5,940	$5,940.00
Travel	$5,700	$1,709	$7,409	$7,408.91
Total Other Direct Costs	**$16,324**	**$3,480**	**$19,804**	**$19,804.41**
Subtotal I-II	**$143,500**	**$55,407**	**$198,907**	**$198,907.48**
Indirect Costs (9%)	**$12,915**	**$4,987**	**$17,902**	**$17,901.67**
III- Consultant/Contractural	**$20,250**	**($18,250)**	**$2,000**	**$2,000.00**
Total All Categories	**$176,665**	**$42,144**	**$218,809**	**$218,809.15**

Year 1 Expenditures	$404,550.55	Total Grant Award	$998,000.00
Year 2 Expenditures	$353,710.65	Less Total Expenditures	($977,070.35)
Year 3 Proposed Expenditures	$218,809.15	Unspent Balance	$20,929.65
Total Expenditures	$977,070.35		

BUDGET NARRATIVE – Revised Items

I. - PERSONNEL

Project Director, David E. Joranson, MSSW, (60%): Revision increases the project director percent effort from 50% to 60% and extends his salary for February through April 2002. Mr. Joranson increased his travel. to speak more target audiences to educate on the issues of pain management policy. He also increased his effort in providing technical assistance and writing manuscripts for the project.

Co-Director, Aaron M. Gilson, PhD, (50%): Revision extends his salary for February through April 2002.

Policy Analyst, Karen M. Ryan, MA, (50%): Revision extends her salary for February through April 2002.

Research Program Administrator, Carolyn M. Williams, MBA, (50%): Revision extends her salary for February through April 2002.

Information Processing Consultant, John M. Nelson, MS: Revision reduces salary amount to reflect amount actually paid. Mr. Nelson left close to the end of the project. Martha Maurer assumed responsibility for management of the policy data base.

Associate Research Specialist, Martha Maurer, BS, (50%): Revision extends her salary for February through April 2002.

Outreach Specialist, Jody Jorenby, BS, (50%): Revision extends her salary for February through April 2002. Ms Jorenby joined the project during the fall of 2002.

Program Assistant, Linda Gorman, (60%): Revision extends her salary for February through April 2002 and increases the percent effort from 50% to 60% to provide more support for data entry for multiple survey projects and increased support for travel arrangements.

Title	Salary Base Rate	Fringe Rate
Project Director	$93,836	32%
Co-Director	$47,590	32%
Project Analyst	$38,884	32%
Research Program Manager	$48,829	32%
Information Processing Consultant	$37,222	32%
Associate Research Specialist	$31,290	32%
Outreach Specialist	$27,000	32%
Program Assistant	$27,683	44.5%

Fringe Benefits: Benefits are provided by the State of Wisconsin and administered by the University of Wisconsin System and include income continuation insurance, unemployment compensation, worker's compensation, social security, health insurance, retirement, and ERA administration.

II. - OTHER DIRECT COSTS

Supplies ($926): Reduced by $7 to reflect actual expenditures.

Computer Supplies ($270): Increased by $20 to reflect actual expenditures.

Duplicating/Printing ($2,587): Reduced by $277 to reflect actual expenditures.

Telephone ($1,207): Increased by $130 to reflect actual expenditures.

Service Agreements ($716): Decreased by $784 to reflect actual expenditures.

Software ($5,940): Reflects cost of subscription to LexisNexis service ($660/month x 9 months). The LexisNexis database services is used to identify policies from state/national statutes and regulations..

Travel ($7,409): Increased by $1,709 to reflect additional travel needed by Project Director, David Joranson, to speak to target audiences to educate on the issues of pain management policy.

III. - INDIRECT COSTS

($17,902): 9% of $198,907, total of Personnel and Other Direct Costs.

IV. - CONSULTANT/CONTRACTUAL

($2,000): Many advisors to the project would not accept an honorarium. Also, the prior test evaluation of policies for 17 states provided enough guidance for the comprehensive review of the remaining states.

SECTION

6

AWARD LETTER, TREASURER'S LETTER, PAYMENT SUMMARY & GRANT SIGN-OFF SHEET

THE
ROBERT WOOD
JOHNSON
FOUNDATION

July 30, 1999

David Ward, Ph.D.
Chancellor
University of Wisconsin-Madison
161 Bascom Hall
500 Lincoln Drive
Madison, WI 53706

Reference: I.D. #036509

Dear Chancellor Ward:

It is a pleasure to inform you that The Robert Wood Johnson Foundation has approved a grant of $998,000 to the University of Wisconsin-Madison Medical School in 30-month continued support of a project to assess states' pain policies, under the direction of David E. Joranson, M.S.S.W. This grant is being made under the Foundation's Targeted End-of-Life Projects Initiative.

The funds are to be used in accordance with the proposal to the Foundation and the terms and conditions outlined in the Request for Project Support, dated January 27, 1999. They are also to be used in accordance with the final budget and are to be applied over the period August 1, 1999, through January 31, 2002.

Our Treasurer's Office will be in touch concerning payment of this grant and reporting requirements. During the period of this grant, any questions you may have should be addressed to Rosemary Gibson, who will have responsibility among our staff for this activity.

If your organization wishes to issue a news release on this grant, please feel free to do so. We ask that a copy of the draft text be sent to us for our review and information in advance of dissemination. Please allow three days for this process. Address the copy to the Foundation to the attention of Maureen Cozine in our Communications Office.

All of us at The Robert Wood Johnson Foundation wish you continued success in carrying out this important undertaking.

Sincerely,

Steve Schroeder

Steven A. Schroeder, M.D.

SS:opm

cc: David E. Joranson, M.S.S.W.
August P. Hackbart

Office of the President and CEO

Route 1 and College Road East Post Office Box 2316 Princeton, New Jersey 08543-2316 (609) 452-8701

Internet: http://www.rwjf.org
e-mail: mail@rwjf.org

THE
ROBERT WOOD
JOHNSON
FOUNDATION

August 11, 1999

David E. Joranson, M.S.S.W.
Director
Pain and Policy Studies Group
University of Wisconsin-Madison
1900 University Avenue
Madison, WI 53705

Reference: I.D. #036509 - Conveyance of Funds, Guidelines, and Forms

Dear Mr. Joranson:

This supplements our recent award letter in regard to your grant for $998,000 in support of the Targeted End-of-Life Projects Initiative: a project to assess states' pain policies.

The Foundation's policy is to disburse your grant funds semi-annually. Your first check for $238,721, which excludes funds budgeted for subcontract(s), is enclosed. We will adjust your payment schedule upon receipt and review of the subcontract(s) or a letter which specifies the contractee, period of performance, workplan/deliverables, and budget and budget narrative. Also enclosed is a Financial Report form. This form should be completed semi-annually and returned to this office when additional cash is needed.

Under extraordinary circumstances, payments may be either accelerated or decelerated. Therefore, you should submit the financial report whenever it becomes evident that your remaining cash balance will be depleted.

As you know, the Request for Project Support and Conditions of Grant form contains a number of specific additional instructions regarding the handling of funds. Since you are responsible for conforming to these instructions, I am attaching a copy for your reference. In addition, a copy of the "Grant Budget Revision Guidelines" and "Financial Reporting/Budgeting Practices," which must be followed if a budget revision becomes necessary, is also attached. Please read these guidelines and practices carefully.

The Robert Wood Johnson Foundation has initiated a program whereby grantees are selected at random to receive an internal audit review. The purpose of this review is to: 1) provide the Foundation with the assurance that our funds are being used for their intended purpose; and 2) provide recommendations to our grantees on methods to improve their organizations. If your organization is selected, you will be notified in advance of the audit.

Annual financial and progress reports on this grant will be due shortly after each budget period. You will receive a reminder in advance of the due date of these reports.

Office of the Vice President and Treasurer

Route 1 and College Road East Post Office Box 2316 Princeton, New Jersey 08543-2316 (609) 452-8701

When submitting all correspondence under your grant, reference the above-captioned grant number. If someone other than yourself will be the financial contact person on this grant, please supply us with that information. The person who has financial responsibility for your grant at the Foundation is Mona L. Hall.

If you have any questions, please contact Ms. Hall at 609-243-5844.

Sincerely,

Peter Goodwin
Vice President and Treasurer

/JEO
Enclosures

cc: [redacted]

FINANCIAL REPORT
The Robert Wood Johnson Foundation
P.O.Box 2316
Princeton, NJ 08543-2316
Phone:(609)452-8701 Fax:(609)452-9564

FA: MLH **PA:** LLM **PO:** RG

Grantee: *University of Wisconsin-Madison Medical School*

Project Director: David E. Joranson (608-263-7662)
Fiscal Officer :

Grant Number: 036509 for [EOL]
Budget Period: May-01-1999 to Apr-30-2000
Grant Period: Aug-01-1999 to Jan-31-2002

Budget for Year : 1
Revised:

EXPENDITURES

Item	Approved Budget Amount	Period 1 05/99-10/99	Period 2 11/99-04/00	Period 3	Period 4	Period 5	Period 6	Total	Variance	Pct
PERSONNEL										
Project Director	78,290									
Co-Director	35,981									
Project Advisor	5,395									
Project Analyst	29,357									
Res. Program Manager	33,994									
Info. Processing Cons	31,980									
Assoc Rsch Spec	24,380									
Outreach Specialist	16,000									
Program Assistant	10,615									
Office Assistant	4,992									
Fringe Benefits	91,489									
Personnel Subtotal	362,473									
OTHER DIRECT COSTS										
Supplies	2,700									
Computer Supplies	500									
Duplicating/Printing	2,865									
Telephone	2,155									
Postage	1,500									
Service Agreements(s)	3,000									
Software	6,500									
Travel	15,960									
Other Direct Subtotal	35,180									
INDIRECT COSTS	35,789									

FINANCIAL REPORT

The Robert Wood Johnson Foundation
P.O.Box 2316
Princeton, NJ 08543-2316
Phone: (609) 452-8701 Fax: (609) 452-9564

FA: MLH **PA:** LLM **PO:** RG

Grantee: *University of Wisconsin-Madison Medical School*

Project Director: David E. Joranson (608-263-7662)
Fiscal Officer :

Grant Number: 036509 for [EOL]
Budget Period: May-01-1999 to Apr-30-2000
Grant Period: Aug-01-1999 to Jan-31-2002

Budget for Year : 1
Revised:

EXPENDITURES

Item	Approved Budget Amount	Period 1 05/99-10/99	Period 2 11/99-04/00	Period 3	Period 4	Period 5	Period 6	Total	Variance	Pct
CONSULTANT/CONTRACTUAL	44,000									
Cons/Contrct Subtotal	44,000									
Grand Total	477,442									

Date Printed
06/16/99

GRANT SIGN-OFF SHEET

I.D.#: 036509 **DATE REC'D:** January 19, 1999

INST:
University of Wisconsin-Madison Medical School
Madison, WI 53706-1532

TITLE:
A project to assess states' pain policies

DOLLARS: ~~$999,997.00~~ $998,000. MH 7/29/99 **MONTHS:** ~~36~~ 30 **START DATE:** 08/01/99

PROJECT DIRECTOR: David E. Joranson

PO: Rosemary Gibson **SO:** Doriane C. Miller

CO: **FO:** Mona L. Hall

PA: Linda L. Manning

ANTICIPATED RENEWAL:

RENEWAL EXPECTED: (YES / (NO)) **ANTICIPATED BOARD DATE:** _____

ESTIMATED DOLLARS: _____ **MONTHS:** _____

RED FOLDER APPROVAL:

FMO: MH **FINAL DOLLARS:** $998,000. **FINAL MONTHS:** 30 MOS.

TREASURER'S OFFICE: Peter [illegible] $998,000 — **DATE:** 7.29.99

VP, GEN. COUNS., & SECRETARY: [signature] **DATE:** 7/29/99

THE ROBERT WOOD JOHNSON FOUNDATION
Project Transaction For Grant [036509] - Status [Closed]

Institution: Board of Regents of the University of Wisconsin System

Project Title: A project to assess states' pain policies

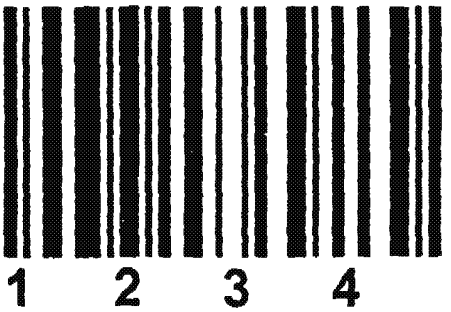
Transaction	Date	Amount	Status	Check/Draft#	Memo
Initialization	07/30/99	998,000.00	Processed		Initalization
Payment	08/11/99	238,721.00	Processed	(C) - 6524	Payment
Payment	04/12/00	168,904.00	Processed	(C) - 13510	
Payment	11/10/00	168,873.00	Processed	(C) - 19531	
Payment	04/23/01	185,075.00	Processed	(C) - 24457	
Payment	11/26/02	203,920.00	Processed	(C) - 41949	
Cancellation	12/09/02	32,507.00	Processed		Change of Authority/Cancellation

Awarded	998,000.00	**Cancellation & Refunds**	32,507.00
Actual	965,493.00	**Payments & Void Checks**	965,493.00
Unpaid Balance	.00		

SECTION

7

PRECIS



GRANTS AWARDED
END-OF-LIFE PMT

EOL

TARGETED END-OF-LIFE PROJECTS INITIATIVE

Foundation Team: Rosemary Gibson, Doriane Miller, Karen Gerlach, Mona Hall, Rona Henry, Emily Snell, Victoria Weisfeld, Merry Wood, Linda Manning

SUMMARY

Purpose: To support projects under $1 million that will advance the Foundation's strategic objectives to improve care at the end of life

Total authorizations: $19.525 million (since January 1998)

Most recent authorization: $12 million for one year (January 1999)

Program status: $17,878,383 expended for 45 grants (includes grants reported below)

$1,646,617 remaining in authorization

I. Award of two program grants, totaling $1,996,865

DEVELOPMENT OF THE NATIONAL RESOURCE CENTER FOR END-OF-LIFE PHYSICIAN EDUCATION
$998,865 for 36 months (9/1/99 - 8/31/02)
Medical College of Wisconsin Inc. -- I.D. 36547

PROJECT TO ASSESS STATES' PAIN POLICIES
$998,000 for 30 months (8/1/99 - 1/31/02)
Previous Support: $87,920 for seven months
University of Wisconsin-Madison Medical School -- I.D. 36509

Medical College of Wisconsin Inc. There is currently no single source or repository for high-quality, peer-reviewed educational materials for end-of-life care. During the past three years, several national projects have been started, directed at all levels of physician education: medical school, post-graduate, and continuing education. As these programs mature, there will be an increased need

for wider dissemination of material as interest broadens in this field. This grant will develop a Web-based educational resource center for end-of-life physician educational materials. All materials will be peer reviewed and will be indexed on the Web site by information such as the intended audience and the specific education objectives of the material. In addition to providing useful palliative care education materials, this research will increase the quality of those materials and provide a forum for exchange of ideas and information.

University of Wisconsin-Madison Medical School. Pain policy is a new arena for many state legislators and other policy makers. To help fill the gap in understanding state pain policy, this project will conduct the first state-by-state assessment of states' laws, regulations, and guidelines regarding the treatment of pain with controlled substances. In addition, the project will highlight specific examples of improvements that states have made in their pain policies to help inform other states about positive changes that can be made and thereby facilitate progressive pain policy in other states. Changes in state policies also will be continuously tracked. Additionally, the Pain and Policy Studies Group will provide technical assistance to grantees in the Foundation's national program, Community-State Partnerships to Improve End-of-Life Care, and to the increasing number of health and government organizations including state medical boards that are developing pain management and end-of-life initiatives. Finally, consistent with the intent of increasing the awareness of pain policy issues and the ability of key individuals and organizations in government and health care to evaluate and improve policies that affect pain management, there will be a proactive outreach component.

II. Award of one communications grant

MONOGRAPH ON CARE OF THE DYING FOR NURSING -- SUPPLEMENTAL SUPPORT
$29,694 for 12 months (9/1/99 - 8/31/2000)
Previous Support: $100,000 for 36 months
University of North Carolina at Chapel Hill School of Nursing -- I.D. 37538

University of North Carolina at Chapel Hill School of Nursing. In 1997, the Foundation provided funding to develop a monograph titled, *Notes on a Peaceful Death*, and to disseminate the information contained therein to members of the nursing profession, under the direction of Edward J. Halloran, R.N., Ph.D. (I.D. 30101). This grant will extend and expand that work. Dr. Halloran's grant resulted in the development of a manuscript suitable for publication and the

convening of a group of nursing influentials to discuss and assist in disseminating the precepts of a peaceful death (December 1998). The group reached two principal conclusions: (1) nurses have a primary role in instituting care that will lead to a peaceful death; and (2) nurses, with the leadership of symposium participants, will lead the effort to improve patient care, starting with an effort to add a fifth vital sign, pain assessment, to the routine taking of vital signs (temperature, pulse, respiration, and blood pressure).

III. Award of two research and evaluation grants, totaling $913,994

RESEARCH AND OUTREACH COMMUNICATIONS ACTIVITIES FOR MISSOULA DEMONSTRATION PROJECT ON THE QUALITY OF LIFE'S END
$699,146 for 24 months (9/1/99 - 8/31/01)
Previous Support: $576,112 for 27 months
Missoula Demonstration Project Inc., Missoula, Montana -- I.D. 36677

DEVELOPMENT AND VALIDATION OF AN INSTRUMENT TO ASSESS QUALITY OF HOSPICE END-OF-LIFE CARE
$214,848 for 24 months (8/1/99 - 7/31/01)
University of Washington School of Medicine -- I.D. 36351

Missoula Demonstration Project Inc. The Missoula Demonstration Project (MDP) was established in March 1996 to research the experience of dying persons and their families and to demonstrate that a community-based approach of excellent medical care and psychological, social, and spiritual support can consistently improve the quality of life among those who are dying and their families. The Missoula community, in a sense, is a living laboratory to demonstrate that improved care at the end of life and enhanced personal experience for individuals and families can be achieved through discussion of individual and community goals. Over the past year, the project has focused on administration and data analysis of the surveys it has conducted, including a retrospective clinical profile of 250 deaths, a faith community leaders survey, a Native American experience assessment, and administration of community and physician surveys in a comparison city of Laramie, Wyoming. Additional results are being finalized for the prospective and retrospective clinical profiles, family bereavement interviews, community focus groups, and patient and family caregiver surveys. As the project moves into its final phase and details the lessons learned, the focus of new activities will turn to communication and dissemination of the findings. The development of a strategic communications plan will enable the MDP to share its

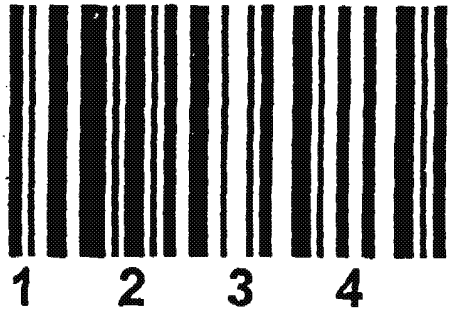
research tools, methodology, and community engagement strategies (with families, institutions, and agencies) with national and local colleagues.

University of Washington School of Medicine. The objective of this project is to develop, validate, and disseminate a questionnaire for measuring the quality of the dying experience for individuals with a chronic or terminal disease. This instrument, called the Quality of Dying and Death, will be administered to family members and health care providers after an individual's death. The questionnaire could be used to examine the relationship between the quality of care at the end of life and the quality of dying; to evaluate interventions designed to improve the quality of dying; and, in research efforts, to describe the quality of dying and death and their correlates. In addition, this project will be the first step to developing a short form of the questionnaire that could be used for continuous quality improvement efforts to improve the dying experience for patients in institutional and home-based hospices, hospitals, nursing homes, and other settings.

SECTION

8

ANNUAL NARRATIVE & FINANCIAL REPORTS & INTERIM FINANCIAL REPORTS



THE
ROBERT WOOD
JOHNSON
FOUNDATION

1/4
EOL
RG
JWS

April 11, 2000

Robert C. Andresen
Administrative Officer
Graduate School, Research and Sponsored Programs
University of Wisconsin-Madison
750 University Avenue, Room 456
Madison, WI 53706-1490

Reference: I.D. #036509 - Transmittal of Next Payment

Dear Mr. Andresen:

This is in reference to your Robert Wood Johnson Foundation grant in support of the Targeted End-of-Life Projects Initiative: a project to assess states' pain policies.

In reviewing your recent financial report, we note that cumulative expenditures as of January 31, 2000, have been $168,904. The Foundation has made payments to date totaling $238,721 leaving you a cash balance as of January 31, 2000, of $69,817. Enclosed with this letter is our check for $168,904. This check equals your next payment less your cash balance. Also enclosed is your financial reporting form for your use when reporting expenditures.

If I can assist you further, please contact me at 609-243-5864.

Sincerely,

Joseph P. Wechselberger
Financial Analyst

/JPW
Enclosures

cc: David E. Joranson, M.S.S.W.
Rosemary Gibson

FINANCIAL REPORT
The Robert Wood Johnson Foundation
P.O.Box 2316
Princeton, NJ 08543-2316
Phone:(609)452-8701 Fax:(609)452-9564

FA: MLH **PA:** JMS **PO:** RG

Project Director: David E. Joranson (608-263-7662)
Fiscal Officer :

Grantee: *University of Wisconsin-Madison Medical School*
Grant Number: 036509 for [EOL]
Budget Period: Aug-01-1999 to Jul-31-2000
Grant Period: Aug-01-1999 to Jan-31-2002

Budget for Year : 1
Revised:

EXPENDITURES

Item	Approved Budget Amount	Period 1 08/99-01/00	Period 2 02/00-07/00	Period 3	Period 4	Period 5	Period 6	Total	Variance	Pct
PERSONNEL										
Project Director	78,290	36,929								
Co-Director	35,981	16,972								
Project Advisor	5,395	0								
Project Analyst	29,357	13,848								
Res. Program Manager	33,994	15,969								
Info. Processing Cons	31,980	15,085								
Assoc Rsch Spec	24,380	11,500								
Outreach Specialist	16,000	2,333								
Program Assistant	10,615	0								
Office Assistant	4,992	1,490								
Fringe Benefits	91,489	35,518								
Personnel Subtotal	362,473	149,644								
OTHER DIRECT COSTS										
Supplies	2,700	1,106								
Computer Supplies	500	174								
Duplicating/Printing	2,865	54								
Telephone	2,155	0								
Postage	1,500	0								
Service Agreements(s)	3,000	695								
Software	6,500	2,334								
Travel	15,960	951								
Other Direct Subtotal	35,180	5,314								
INDIRECT COSTS	35,789	13,946								

FINANCIAL REPORT
The Robert Wood Johnson Foundation
P.O.Box 2316
Princeton, NJ 08543-2316
Phone: (609) 452-8701 Fax: (609) 452-9564

FA: MLH **PA:** JMS **PO:** RG

Project Director: David E. Joranson (608-263-7662)
Fiscal Officer :

Grantee: ***University of Wisconsin-Madison Medical School***
Grant Number: **036509** for [EOL]
Budget Period: Aug-01-1999 to Jul-31-2000
Grant Period: Aug-01-1999 to Jan-31-2002

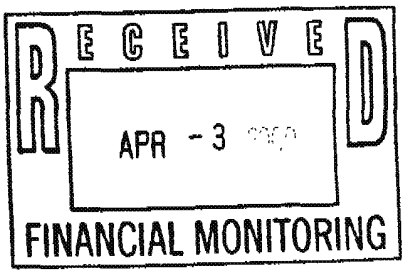
Budget for Year : 1
Revised:

EXPENDITURES

Item	Approved Budget Amount	Period 1 08/99-01/00	Period 2 02/00-07/00	Period 3	Period 4	Period 5	Period 6	Total	Variance	Pct
CONSULTANT/CONTRACTUAL	44,000	0								
Cons/Contrct Subtotal	44,000									
Grand Total	**477,442**	**168,904**								

University of Wisconsin-Madison
Graduate School, Research and Sponsored Programs

March 28, 2000



Mona L. Hall
Financial Analyst
The Robert Wood Johnson Foundation
Route 1 and College Road East
P. O. Box 2316
Princeton, NJ 08543-2316

In reply, please refer to
UW Acct No. 133-CW36

RE: Grant #036509

Dear Ms. Hall:

Enclosed is the interim financial report for Year 1 on the above-referenced grant for the period August 1, 1999 through January 31, 2000 under the direction of David E. Joranson.

Thank you for your support of this project. If you have any questions regarding this report, please contact me at 608/262-9028.

Sincerely,

Mary C. Koscielniak

Mary C. Koscielniak
Accountant

Enclosure
cc: Joranson, David E – Med Schl Pain Study
Williams, Carolyn M – Med Schl Pain Study
Medical School Fiscal Services
File

400 A.W. Peterson Building
750 University Avenue
Madison, WI 53706-1490

Telephone (608) 262-3822
Fax (608) 262-5111

FINANCIAL REPORT
The Robert Wood Johnson Foundation
P.O. Box 2316
Princeton, NJ 08543-2316
Phone: (609) 452-8701 Fax: (609) 452-9564

UW Account #133-CW36

FA: MLH PA: LLM PO: RG
Project Director: David E. Joranson (608-263-7662)
Fiscal Officer: Robert C. Andresen (608-262-2896)

Grantee: **University of Wisconsin-Madison**
Grant Number: 036509 for (EOL)
Budget Period: Aug-01-1999 to July-31-2000
Grant Period: Aug-01-1999 to Jan-31-2002

Budget for Year: 1
Revised:

Item	Approved Budget Amount	EXPENDITURES Period 1 08/99-01/00	Period 2 02/00-07/00	Total	Variance
PERSONNEL					
Project Director	78,290.00	36,929.28		36,929.28	41,360.72
Co-Director	35,981.00	16,972.20		16,972.20	19,008.80
Project Advisor	5,395.00	-		-	5,395.00
Project Analyst	29,357.00	13,847.88		13,847.88	15,509.12
Res Program Manager	33,994.00	15,969.06		15,969.06	18,024.94
Info Processing Cons	31,980.00	15,084.90		15,084.90	16,895.10
Assoc Rsch Spec	24,380.00	11,500.02		11,500.02	12,879.98
Outreach Specialist	16,000.00	2,333.34		2,333.34	13,666.66
Program Assistant	10,615.00	-		-	10,615.00
Office Assistant	4,992.00	1,490.30		1,490.30	3,501.70
Fringe Benefits	91,489.00	35,517.84		35,517.84	55,971.16
Personnel Subtotal	362,473.00	149,644.82		149,644.82	212,828.18
OTHER DIRECT COSTS					
Supplies	2,700.00	1,106.21		1,106.21	1,593.79
Computer Supplies	500.00	173.53		173.53	326.47
Duplicating/Printing	2,865.00	53.72		53.72	2,811.28
Telephone	2,155.00	-		-	2,155.00
Postage	1,500.00	-		-	1,500.00
Service Agreements	3,000.00	694.94		694.94	2,305.06
Software	6,500.00	2,333.80		2,333.80	4,166.20
Travel	15,960.00	950.83		950.83	15,009.17
Other Direct Subtotal	35,180.00	5,313.03		5,313.03	29,866.97
INDIRECT COSTS	35,789.00	13,946.17		13,946.17	21,842.83
CONSULTANT/CONTRACTUAL					
Cons/Contrct Subtotal	44,000.00	-		-	44,000.00
Grand Total	**477,442.00**	**168,904.02**		**168,904.02**	**308,537.98**

Robert C. Andresen
Robert C. Andresen, Admin. Officer
Research & Sponsored Programs

P-43071 _ 00091

THE
ROBERT WOOD
JOHNSON
FOUNDATION

1/4 EOL
RG
JMS

April 7, 2000

David E. Joranson, M.S.S.W.
Director
Pain and Policy Studies Group
University of Wisconsin-Madison
1900 University Avenue
Madison, WI 53705

Reference: I.D. #036509 - Reports Due

Dear Mr. Joranson:

This is a reminder that both the annual financial and annual progress reports for your grant in support of the Targeted End-of-Life Projects Initiative: a project to assess states' pain policies will be due in May. The financial report should be in the same format as the approved grant budget. Guidelines for the completion of the annual progress report are attached. Please direct these reports to my attention.

If you anticipate any difficulty in submitting these reports by May 31, 2000, kindly contact me.

Sincerely,

Mona L. Hall

Mona L. Hall
Financial Analyst

MLH\sam - SITES
Enclosure

cc: [redacted]

Office of the Vice President and Treasurer

Route 1 and College Road East Post Office Box 2316 Princeton, New Jersey 08543-2316 (609) 452-8701

THE
ROBERT WOOD
JOHNSON
FOUNDATION

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September 11, 2000

Carolyn M. Williams, MBA
Research Program Administrator
UW Comprehensive Cancer Center
University of Wisconsin-Madison
1900 University Avenue
Madison, WI 53705

CENTRAL FILES
PERMANENT COPY

Reference: I.D. #036509 - Acknowledgement of Annual Progress Report

Dear Ms. Williams:

This is in reference to your Robert Wood Johnson Foundation grant in support of the Targeted End-of-Life Projects Initiative: a project to assess states' pain policies.

We have received your annual progress report and have forwarded a copy of this report to Rosemary Gibson for her review. If she has any questions or comments, she will contact you directly.

If I can assist you further, please contact me at 609-243-5844.

Sincerely,

Sophia Kounelias
Financial Analyst

/SXK
Enclosure

cc: Robert C. Andresen
Rosemary Gibson
David E. Joranson, M.S.S.W.

Office of the Vice President and Treasurer

Route 1 and College Road East Post Office Box 2316 Princeton, New Jersey 08543-2316 (609) 452-8701

PAIN & POLICY STUDIES GROUP

WHO Collaborating Center
for Policy and Communications
in Cancer Care

August 31, 2000

Sophia Kounelias
Financial Analyst
Robert Wood Johnson Foundation
Route 1 and College Road East
Princeton, NJ 08543-2316

Reference: Grant # 036509

Dear Ms. Kounelias,

Enclosed you will find three copies of the Annual Progress Report, three copies of the Bibliography, and two copies of the Communications Products for the above referenced grant.

The financial report for this project will be forwarded to you directly from the Research and Sponsored Programs department of the University of Wisconsin.

Under separate cover, you will be receiving a request to carry over funds and a rebudget for year two of this project. If you have any questions, you may contact me directly at 608-263-7371.

Sincerely,

Carolyn M Williams

Carolyn M. Williams, MBA
Research Program Administrator

PAIN & POLICY STUDIES GROUP

WHO Collaborating Center
for Policy and Communications
in Cancer Care

ANNUAL PROGRESS REPORT
YEAR 1

"BUILDING CAPACITY TO PROMOTE PAIN POLICY THROUGH EVALUATION, RESEARCH AND COMMUNICATION"

TARGETED END-OF-LIFE INITIATIVES

GRANT # 036509
AUGUST 1, 1999 -JULY 31, 2000

SUBMITTED
AUGUST 31, 2000

PAIN & POLICY STUDIES GROUP
1900 UNIVERSITY AVE.
MADISON WI 53705-4013
608.263.7662
PPSG@MED.WISC.EDU

1. WHAT WERE THE PROJECT'S OBJECTIVES AND HOW HAS THE PROJECT MET THEM IN THIS YEAR?

A review of the project's time-line demonstrates that most of the objectives proposed during the first year have been met in a timely fashion.

Part 1: Policy Evaluation

The document "Achieving Balance in Federal and State Pain Policy: A Guide to Evaluation" was completed in July 2000. The document presents the results of a systematic evaluation of pain-related policies from the federal government and the 50 states. All policies that were in force and available through March 2000 were examined using a set of well-documented criteria based on a Central Principle that should underlie all pain policy. The document is designed as a workbook to assist professionals and groups who want to learn how to evaluate policies that can affect pain management in their state or at the federal level.

The document has been prepared in a hard-copy format and will be disseminated by the end of summer to all Robert Wood Johnson Foundation (RWJF)-supported Community-State Partnerships, other grantees including Last Acts, and to State Cancer Pain Initiatives, State Medical Societies and many other organizations. The document also is being prepared in an electronic format to be placed on the PPSG website. The policy matrices contained in the documents will be automated so that clicking on a dot in a cell will link the user directly to a down-loadable electronic document with the full text and citation of the provision. Completion of the electronic matrices will be accomplished as soon as possible but no later than December 31, 2000. Finally, the document will be put on CD-ROM in a variety of formats and will be available to distribute at any time to organizations or individuals who make this request.

An "Annual Review of New State Pain Policies" currently is being prepared that summarizes all new or amended pain policies from the previous year, such as the adoption of intractable pain treatment acts and medical board regulations and guidelines on prescribing controlled substances for pain. The Annual Review will contain (a) the cumulative trend of pain policies since 1980, and (b) a state-by-state listing, citation, summary, and commentary for each new policy in the previous year.

Although the Annual Review was proposed to be completed by the end of August 2000, we have modified this objective so that it will be completed by the end of December to be able to evaluate all policies adopted in calendar 2000. As a result, the Annual Review will represent a full year, rather than a partial year of policy development. Once completed, the Annual Review will be made available on our website and will be distributed to key individuals and organizations such as health-care providers, patient advocacy groups, state cancer pain initiative, state government pain commissions, state pain summit meetings and task forces, state legislatures, and medical boards.

The PPSG continually updates the electronic access to state pain policies, enhancing its down-loadable website database of the full text of pain policies currently in force. These policies include relevant federal and state laws, regulations, and guidelines. The accuracy and completeness of this policy database is continued to be assured through our current internal quality-control procedure and our regular monitoring of the policy environment. To obtain policies not available by using our electronic legal database (Lexis, from "Lexis-Nexis Research Software"), PPSG staff will contact the appropriate state agency.

Part 2: Empirical Research

PPSG staff continues to collect data regarding the abuse and medical use of opioid analgesics. Abuse data are collected from the Drug Abuse Warning Network (DAWN) of the Substance Abuse and Mental Health Services Administration (SAMHSA), and medical use data come from the Automation of Reports and Consolidated Orders System (ARCOS) of the Drug Enforcement Administration (DEA). Our previous research with these data demonstrated that the abuse of opioid analgesics has remained very low and stable over time despite a substantial increase in their medical use and has been published recently in the *Journal of the American Medical Association*. Efforts are being made to monitor these data to evaluate possible significant changes in their trends in recent years.

Part 3: Communications

A major purpose of this grant is to increase awareness of pain policy issues and to support the efforts of individuals and organizations in government and health care to evaluate and improve policies that affect pain management. We proposed to accomplish this goal through several means, including proactive communication of the products from this grant to a broad range of individuals and groups, using means in addition to the ordinary channels of publishing articles in journals. We proposed to: (1) maintain the PPSG website as a source of pain policy information for the public, (2) expand the PPSG list-serve, and (3) provide rapid and efficient technical assistance and dissemination of information. PPSG established a Communications Team to guide efforts to accomplish this objective. More detail is available in our response to Question 5; a summary of the accomplishments follows.

(1) Website: The Team implemented a number of improvements to the website, including an enhanced home-page and site guide, addition of the full text of many new state pain policies, and addition of new links to the site (see Bibliography). We provided pain experts with slides that they can use when they mention our website in their talks. Utilization of the site has continued to increase, with approximately 3,300 users per month and a total of about 15,000 hits on our website over this same time-period.

(2) List-serve: We reviewed this objective and decided that managing a single list-serve had a limited potential for communicating to the broad audience that is interested in pain policy. We decided that it would be preferable for our staff to monitor and participate actively in the growing number of list-serves on topics that relate to pain policy, rather than manage a list-serve aimed at a more limited subscriber audience. We now participate in list-serves of other groups that are

interested in oncology and pain, substance abuse, prescription monitoring, pain, and end-of-life issues. Typically, we notify these list-serves of our website, respond to questions and note the availability of particular resources that we have developed. We also post our own questions on a variety of list-serves to stimulate discussion and obtain feedback on policy issues. We believe that this approach has resulted in bringing a greater awareness of our work to a much broader audience of professionals.

(3) Technical assistance and dissemination of information: PPSG has provided considerable technical assistance to a variety of groups that have the potential to influence pain policy, including the American Bar Association Commission on Legal Problems of the Elderly, the RWJF Community-State Partnership in Kansas, the Midwest Bioethics Center, the American Academy of Neurology, a joint committee of three national associations, the American Pain Society, the American Society of Addiction Medicine, and the American Academy of Pain Medicine, and to several state cancer pain initiatives.[1] A more detailed description of key technical assistance activities is as follows:

(a) The PPSG assisted the American Bar Association Commission on Legal Problems of the Elderly in its preparation of a position statement on a Proposed ABA Policy on Legal Obstacles to Effective Pain Management.

(b) PPSG was invited by the RWJF Community-State Partnership in Kansas to provide a day's worth of technical assistance on issues and opportunities in regulatory policy in the state. PPSG used this opportunity to prepare a protocol for providing technical assistance in the states.

(c) The PPSG provided comments on a proposed position statement about pain management and public policy to the American Academy of Neurology.

(d) The PPSG provided extensive policy assistance to a joint committee to achieve consensus on terms related to pain and addiction; the committee was established by three national associations: the American Pain Society, the American Society of Addiction Medicine, and the American Academy of Pain Medicine.

(e) The PPSG provided preliminary technical assistance about state prescription monitoring programs to representatives of the Michigan Cancer Pain Initiative and the Hawaii Cancer Pain Initiative. We also compiled and sent an extensive list of the resources available, and are waiting to determine if additional assistance is requested.

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[1] It has been especially rewarding for the PPSG to collaborate with Midwest Bioethics Center and the Community-State Partnerships; these groups are well-organized, committed to the task of improving patient care and decision-making, thoughtful about the role of policy, and are highly professional.

As interests in pain management and end-of-life care expand, requests for our assistance and for providing information sometimes exceed our capacity to respond (and still accomplish our other work under the grant). It is clear that we are working on a dynamic policy stage with multiple actors, different sets and several scenes unfolding simultaneously. We developed an electronic data collection form, as well as a procedure to use it in order to assure we capture the full extent of our technical assistance efforts.

Within the last year, the PPSG Communications Team developed a strategy for publicizing several articles that are going to be published in major journals. We used the dissemination of our April 5, 2000 article in the *Journal of the American Medical Association* as the model. The first component was to ensure that the article and press release were clear about the message (increasing trend in use of opioids for pain yet low and stable abuse trends). The second component was to disseminate this message to our main audiences, including health professional groups, government, and the public.

2. WHAT INTERNAL CHALLENGES WERE ENCOUNTERED DURING THIS YEAR THAT ARE RELATED TO THE PROJECT'S DESIGN, COLLABORATIONS, STAFFING, OPERATIONS, OR OTHER PROJECT FACTORS?

The most significant internal challenge encountered by this project was the development of a program to organize the communication activities of staff members. A Communications Specialist position was created and an individual hired into the position. The person that we hired did not work out and was asked to leave. This gave us the opportunity to re-evaluate our needs and the skills needed for the position. We then decided to hire a Communications Strategist and link this person with a current staff member who would fulfill the role of Communications Coordinator. We have developed a relationship with Renie Schapiro, a Senior Communications Consultant who is helping us develop a communications strategy including defining our target message for each of our products and assisting us in working with the media. Jessica Nischik, a Policy Specialist with the group who has a background in business and marketing, has become our Communications Coordinator. We believe that this arrangement best meets the needs of the group with our goal of communicating the availability of our work and communicating our message of creating a balanced public pain policy.

3. WHAT CHALLENGES OR SUCCESSES WERE CAUSED BY FACTORS EXTERNAL TO THE PROJECT?

A few external factors created challenges and successes for the grant projects. In terms of data collection, two factors made it difficult for us to create a comprehensive, up-to-date database of policies: (1) the dynamic policy environment, and (2) an inability to efficiently obtain policies from state agencies. First, for the purpose of completing the Evaluation Guide (as well as the

Annual Review of State Pain Policies), PPSG staff needed to be aware of recent policy activity at the federal and state levels. There had not, however, been previously-established procedures for proactively obtaining federal and state policies. Given our nascent policy collection methodology, coupled with the extremely dynamic nature of the current policy environment, it was initially difficult to maintain the policy database. Second, although an electronic legal database (Lexis, from "Lexis-Nexis Research Software") was utilized to identify and collect relevant statues for all states and at the federal level, this database could not be used to obtain some state regulations and all policies created by state agencies or organizations (i.e., Medical Boards, Pharmacy Boards, etc.). As a result, PPSG staff needed to spend a considerable amount of time contacting each relevant state agency to evaluate the extent of policy development, adoption, or amendment. This type of data collection was impeded further by Board members who typically did not know about recent or past policy development by their state Board.

In addition, the projects proposed during the first year of the grant, especially the Evaluation Guide, were extraordinarily well timed to provide assistance to the numerous state-level activities that are promoting improvements in pain management and end-of-life care, although responding to opportunities and requests has necessitated some reallocation of grant resources. For example, the growing number of state end-of-life task forces, commissions and initiatives in the US has resulted in an increasing number of requests for information about pain-related policy. Our work is in demand by these groups and, although much of our work is available on the website, this is not always sufficient for such requests. For example, extensive materials were prepared in response to requests from California, Michigan, and Hawaii in relation to their current prescription monitoring programs. It is likely that there will be continuous increases in requests for information and technical assistance, particularly since organizations are sponsoring more and more state-level initiatives. Many of these state initiatives will want to evaluate the need for legislation in the area of pain management in their state. In some cases, there seems to be an unrealistic expectation that legislation is the answer, so we continuously find ourselves explaining the benefits and risks of legislation and other policy approaches.

There also will be an attempt to couple the contents of the Evaluation Guide with the upcoming Bill Moyers television program about end-of-life care. We are working currently with Renie Schapiro, Senior Communications Consultant, to identify ways that this material can be integrated into the press coverage surrounding the Moyers special.

4. IF YOU ARE WORKING IN COLLABORATION WITH OTHER ORGANIZATIONS, OR DEPEND ON OTHER ORGANIZATIONS OR INSTITUTIONS TO MEET THE OBJECTIVES OF THIS PROJECT, HOW ARE THOSE RELATIONSHIPS WORKING?

The PPSG has relied on data from two organizations to support our study of medical consumption and abuse of opioid analgesics: the Drug Enforcement Administration (DEA) and

the Substance Abuse and Mental Health Services Administration (SAMHSA). We request the consumption data for individual opioid analgesics directly from the DEA Targeting and Analysis Unit of the Office of Diversion Control, which has been extremely responsive to our various requests. The Unit provides us with both hard-copy and disk-copy of the Automation of Reports and Consolidated Orders System (ARCOS) data on which our analysis of consumption is based.

The data for abuse of opioid analgesics come from the Drug Abuse Warning Network (DAWN), which is an annual report of SAMHSA within the U.S. Department of Health and Human Services. For the years prior to 1998, the main data tables were available in the hard-copy reports that we obtained from SAMHSA. Starting in 1998, these data tables are available on-line. In addition, for every year of data, we have requested special data runs from SAMHSA for three purposes: (1) to determine the abuse of morphine, which is aggregated with heroin as an abuse category; (2) to determine the abuse of fentanyl when necessary, whose abuse often falls below SAMHSA's reporting cutoff; and (3) to determine the contents of a drug category called "Other/unspecified Narcotic Analgesics." Overall, our experience working with the staff at SAMHSA has been very positive. At one time, however, we faced the possibility of SAMHSA charging us for the special data runs. This situation seemed to arise after we had queried them about extensive future data runs. We overcame this potential problem by reverting to our original, occasional, targeted data runs on an as-needed basis.

Our collaboration with these groups resulted in an article in the *Journal of the American Medical Association* (JAMA) on April 5, 2000 on the medical use and abuse of opioid analgesics. As a result of this publication, staff members at SAMHSA wrote a letter to the editor of JAMA outlining some of the changes that the DAWN data-base will undergo, partly in response to some of the difficulties we experienced in using the data. Their letter was published alongside a letter from us in JAMA (August 2, 2000), commending them for their intended improvements and suggesting additional changes to the database.

5. WHAT HAVE BEEN THE PROJECT'S KEY COMMUNICATIONS ACTIVITIES DURING THE PAST YEAR?

PPSG Website

The PPSG website has been in service since July 1997. In the past 12 months, the website has averaged 14,908 hits and visits by an average of 3,299 users per month from around the world.

The website is currently maintained by the PPSG's Information Technology Manager. Maintaining the website involves updating an interactive matrix of policies adopted by state and national boards, legislatures and organizations, adding the new policies as hypertext markup language (HTML) documents, periodically checking website links to insure that they are current and functional, and making any necessary changes to the format of website pages. Monthly

reports are generated to track the number of website hits and users, and to determine which policy documents are viewed most often by these users. The website e-mail account is also checked daily for user feedback, which is then directed to the proper PPSG staff member(s).

During the grant period there were 12 new policies enacted by state legislatures, state medical boards, state pharmacy boards, and national organizations. These policies were obtained by our policy analysts and converted to WordPerfect format either by scanning a hard copy or converting an already-extant electronic document in another file format. From there they were converted to HTML documents, formatted in the style of other PPSG website documents, and then uploaded to our website.

The July 2000 Pain & Policy Studies Group publication "Achieving Balance in Federal and State Pain Policy: A Guide to Evaluation" was recently made available on the PPSG website in three different ways. The first of these is the full document in Adobe Acrobat (PDF) format, which the viewer can open through the website and view on his/her browser. The second is an interactive PDF version of the document that permits the viewer to look at any particular section of the document s/he wishes, without having to wait for the entire file to load into his or her computer. The third way is an interactive HTML version of the document which can be viewed using virtually any web browser. This interactive HTML version also permits the viewer to see any part of the document without having to wait for the entire document to load. Additional options that the viewer has is to download a self-extracting version of the entire document, and to submit a request for a free hard copy.

Index of PPSG website "top" pages:

- Home-Page
- About the PPSG
- Matrix of State Laws, Regulations, and Guidelines
- Policy Alerts
- PPSG International Policy
- PPSG Bibliography
- PPSG Links to Other Sites
- PPSG Glossary
- U.S. Pain Policies

Other Communication Efforts

In addition to the activities relating to the website, list-serve and technical assistance mentioned under Question 1, the following description provides further information about key activities. Complete information about the communication activities are available in the bibliography.

Publicity for the article published in the *Journal of the American Medical Association.* We believe that we were successful in reaching our key audiences: We mailed a copy of the article and press release directly to all state medical and pharmacy boards and state medical societies; we notified a large number of individuals and organizations via an e-mail broadcast of the availability of the article on our website; the article and its press release are on our website are frequently accessed by users; there were (and continue to be) numerous placements in media aimed at the public (e.g., TIME Magazine, AMA Radio, Healthwatch CNN) and at health professionals (e.g., Oncology Times, WebMD and WebRN, Last Acts). We prepared a special "PPSG News Clipping Report" to capture all the placements. Institutional newsletters are now picking up the story. The details of these placements can be found under Question 5.

Testimony to the Congress. David Joranson testified on October 13, 1999 at a U.S. Senate Committee Hearing on Pain Management and Improving End-of-Life Care. He was invited in writing by Senator Edward M. Kennedy, Ranking Minority Member of the Senate Committee on Health, Education, Welfare, and Pensions. Mr. Joranson testified for information, particularly with respect to the risks to pain management of amending federal controlled substances law to prohibit assisted suicide.

Presentations at national conferences. PPSG provided presentations on trends and issues in pain policy to participants at a number of conferences sponsored by national organizations. Among these were the American Pharmaceutical Association, the American Alliance of Cancer Pain Initiatives, and the Community-State Partnerships.

6. WHAT ARE THE PROJECT'S OTHER SOURCES OF SUPPORT?

This project has no other sources of support. The other activities of the group are international projects related to our status as The World Health Organization Collaborating Center for Policy and Communications in Cancer Care.

Office space for the Pain & Policy Studies Group and this project is provided by the School of Medicine of the University of Wisconsin-Madison.

7. WHAT ARE YOUR PLANS FOR THE PROJECT NEXT YEAR?

The second year of our grant will involve the continuation of many activities conducted during the first year, as well as those scheduled to begin in 2001.

Part 1: Policy Evaluation

We will publish another "Annual Review of New State Pain Policies" to demonstrate policy change throughout 2001. To accomplish this, we will need to continue to monitor the frequency of adoption of new intractable pain treatment policies, as well as regulations and medical board policies that relate to the use of controlled substances for pain. Again, the Annual Review will

be made available on our website and will be distributed to key individuals and organizations such as health-care providers, patient advocacy groups, state cancer pain initiative, state government pain commissions, state pain summit meetings and task forces, state legislatures, and medical boards.

The PPSG will continue to update its electronic access to state pain policies, including the most recent relevant federal and state laws, regulations, and guidelines.

We will complete one of two proposed evaluations of medical board pain guidelines. This first analysis will compare the descriptive results from our evaluation of 24 medical board policies conducted in 1998 (under Grant #031461: "Pain Management and State Regulatory Policy") to those policies adopted subsequent to the first evaluation. An effort will be made to evaluate the extent that "newer" policies contain language that is balanced in recognizing the medical use of controlled substances, is more direct in addressing physicians' concerns about investigation, and is more accurate in the use of terminology.

Part 2: Empirical Research

PPSG staff will continue to collect data regarding the abuse and medical use of opioid analgesics. Abuse data will be collected from the Drug Abuse Warning Network (DAWN) of the Substance Abuse and Mental Health Services Administration (SAMSHA), and medical use data will come from the Automation of Reports and Consolidated Orders System (ARCOS) of the Drug Enforcement Administration (DEA). We will monitor these data to evaluate possible significant changes in their trends in recent years.

Part 3: Communications

The Communications Team plans a number of activities to improve the visibility and understanding of the work done by the PPSG. The PPSG has hired a senior communications consultant, Ms. Renie Schapiro, to assist in the development of its communications strategy. We have designated one staff member, Ms. Jessica Nischik, as communications coordinator. Ms. Nischik has a background in marketing and, as a member of our policy evaluation team, is well informed about the work done by the Group.

PPSG will disseminate the Evaluation Guide to a wide audience of individuals and organizations in government and health care. We will collaborate with key national organizations to disseminate the Evaluation Guide, including the American Alliance for Cancer Pain Initiatives, the National Council of State Legislatures and the Community State Partnerships for End-of-Life Care.

The Communications team is planning dissemination strategies for each of the articles it will publish in the coming year. These articles include:

Gilson AM, Joranson DE. "Controlled Substances and Pain Management: Changes in Knowledge and Attitudes of State Medical Regulators" *Journal of Pain and Symptom Management* (in press)

Joranson DE, Gilson AM; "Federal and State Policy Issues in the Use of Opioids for Treatment of Pain in Patients who Abuse Controlled Substances" *Journal of Maintenance in the Addictions* (in press) (Note: may be published by editor as book chapter rather than part of a theme issue of journal)

Joranson DE, Gilson, AM; "Pharmacists' Knowledge and Attitudes About Opioid Pain Medications in Relation to Federal and State Policy" *Journal of the American Pharmaceutical Association* (in press)

Joranson DE, Gilson AM, Dahl JL, Haddox JD "Pain Management, Controlled Substances, and State Medical Policy: A Decade of Change" *Journal of the American Medical Association* (second revision)

The strategies will ensure that the message is clear, and will make use of press coverage, targeted mailings, e-mail broadcast notification, website placement and possible national news coverage.

The PPSG will improve its media readiness is several ways. We will develop a media kit that contains an informational brochure about the PPSG, as well as fact sheets, staff biographies and photographs, and a Rolodex card for distribution.

The PPSG would like the opportunity to brief Congressional staff on resources available for improving pain policy and would appreciate such assistance from the Foundation.

8. HOW DO YOU ASSESS THE NPO'S ROLE IN YOUR GRANT?

We are appreciative of the Robert Wood Johnson Foundation's support of this project and the very natural flow of information and expression of ideas and issues between the staff members of the PPSG and the staff of RWJ. The *Last Acts* program and the Midwest Bioethics Center has been very helpful with the dissemination of information.

9. HOW LONG HAVE YOU SERVED AS PROJECT DIRECTOR?

David E. Joranson, MSSW has served as the Director of the Pain & Policy Studies Group since it's inception in 1996. He has served as director of this project for the life of the proposal.

PAIN & POLICY STUDIES GROUP

WHO Collaborating Center
for Policy and Communications
in Cancer Care

ANNUAL PROGRESS REPORT BIBLIOGRAPHY
YEAR 1

"BUILDING CAPACITY TO PROMOTE PAIN POLICY THROUGH EVALUATION, RESEARCH AND COMMUNICATION"

TARGETED END-OF-LIFE INITIATIVES

GRANT # 036509
AUGUST 1, 1999 -JULY 31, 2000

SUBMITTED
AUGUST 31, 2000

PAIN & POLICY STUDIES GROUP
1900 UNIVERSITY AVE.
MADISON WI 53705-4013
608.263.7662
PPSG@MED.WISC.EDU

BIBLIOGRAPHY

Books and Reports

*Joranson DE, Gilson AM, Ryan KM, Maurer MA, Nischik JA, Nelson JM. *Achieving Balance in Federal and State Pain Policy: A Guide to Evaluation.* Madison, Wisconsin: Pain and Policy Studies Group, University of Wisconsin Comprehensive Cancer Center, 2000. 500 copies printed, dissemination pending.

Articles

*Gilson AM, Joranson DE. "Controlled Substances and Pain Management: Changes in Knowledge and Attitudes of State Medical Regulators" *Journal of Pain and Symptom Management.* Forthcoming.

*Joranson DJ, Ryan KM, Gilson AM, Dahl JL. "Trends in Medical Use and Abuse of Opioid Analgesics." *Journal of the American Medical Association.* 282 (April 5): 1710-1714, 2000.

*Joranson DJ, Ryan KM, Gilson AM, Dahl JL. "Letter to the Editor: In Reply to 'Reporting Drug Abuse in the Emergency Department.'" *Journal of the American Medical Association.* 284 (August 2): 564, 2000.

*Joranson DE, Gilson AM. "Federal and State Policy Issues in the Use of Opioids for Treatment of Pain in Patients who Abuse Controlled Substances." *Journal of Maintenance in the Addictions*. Forthcoming.

*Joranson DE, Gilson AM, Dahl JL, Haddox JD. "Pain Management, Controlled Substances, and State Medical Policy: A Decade of Change." *Journal of the American Medical Association.* Forthcoming.

*Joranson DE, Gilson, AM. "Pharmacists' Knowledge and Attitudes About Opioid Pain Medications in Relation to Federal and State Policy." *Journal of the American Pharmaceutical Association*. Forthcoming

Joranson DE, et.al. "Pain Management and Prescription Monitoring." Unpublished.

Presentations and Testimony

David E. Joranson, "Trends and issues in pain-related policies: laws and state medical board guidelines," at Contemporary Concepts in Cancer Pain: Tenth Annual Conference of the Pennsylvania Cancer Pain Initiative, Pennsylvania Cancer Pain Initiative, September 23, 1999.

*David E. Joranson, "Testimony of David E. Joranson," at the U.S. Senate Hearing on Pain Management and Improving End of Life Care, October 13, 1999, Washington D.C., Requested by Senator Edward Kennedy, October 1, 1999.

David E. Joranson, "Trends and issues in state pain policy," at Health Care and Law in the New Millennium: Patients' Rights at the Forefront, the American Association of Nurse Attorneys, October 22, 1999, Denver, Colorado.

David E. Joranson, "Evaluation of state pain policy: is it balanced?" at Pain Management: Medical, Legal and Ethical Issues, Baystate Health System Office of Continuing Education, November 10, 1999, Holyoke, Massachusetts.

David E. Joranson, "Guidelines, trends and issues in the state pain-related policy," at the 21st Annual Cancer Symposium: Palliative Issues and Supportive Care in the Cancer Patient, Northwest Community Hospital, November 13, 1999, Arlington Heights, Illinois.

David E. Joranson, "Improving Pain Management Strategies," at Technical Consultation for the Life Project, Kansas Community State Partnership, December 14, 1999, Kansas City, Kansas.

David E. Joranson, "Overview of regulatory history," at Chronic Pain: Medical Management and Regulatory Issues, North Broward Hospital District, April 8, 2000, Pompano Beach, Florida.

David E. Joranson, "Controlled substances: opioids for chronic pain and the anxious physician," at the Pain Management Seminar, Purdue Pharma L.P., April 18, 2000, Des Moines, Iowa.

David E. Joranson, "Progress and issues in pain policy," at Continuing Education in Pain Management, VA Hospital, May 4, 2000, Northport, New York.

David E. Joranson, "Developments in national and state policies affecting pain management: national update on policies and legislation," at the 11th National Meeting for State Cancer Pain Initiatives, American Alliance of State Cancer Pain Initiatives, June 16, 2000, Kansas City, Missouri.

World Wide Web Sites

*www.medsch.wisc.edu/painpolicy
Provides full text of individual state pain policies and pain related federal policies, links to other pain organizations, a glossary of terms and full text of articles published by the PPSG. Madison, WI: Pain & Policy Studies Group. Estimated 3,299 visits per month.

Press Kits and News Releases

*A news release on the *Journal of the American Medical Association* article "Trends in Medical Use and Abuse of Opioid Analgesics", mailed by JAMA on March 30, 2000 to 1500 reporters

nationally. Also accessible to over 2,000 domestic and international journalists through "EurekAlert!" (a Web site for journalists maintained by the American Association for the Advancement of Science).

*A news release on the *Journal of the American Medical Association* article "Trends in Medical Use and Abuse of Opioid Analgesics", mailed by the PPSG on April 1, 2000 to 413 state medical societies, state medical boards, state boards of pharmacy, attorney generals, grant advisors, academic leaders and pain management advocates. One hundred sixty-six academic leaders, pain management advocates, newsletters, professional societies and listserves were notified through email.

Print Coverage

*"States are relaxing rules on painkillers: Improving care at the end of life," in *The States*, May 1999.

*"Web Site Offers Pain Management Policy Information," in the *Oregon State Board of Pharmacy Newsletter*, August 1999.

*"Can doctors put their fears to rest?" in *Medical Economics,* February 21, 2000.

*Highlight: The Pain & Policy Studies Group (PPSG)," in *ASPMN Pathways*, March/April 2000.

*"More opiates used to treat severe pain," in *Reuter's Health Information*, April 4, 2000.

*"Abuse of opioid painkillers by patients is uncommon, study finds," in *Oncology Times*, April 5, 2000.

*"High use of narcotic painkillers is not linked to abuse," in *The Oregonian*, April 5, 2000.

*"Study finds drugs for pain not abused: Results support efforts to manage pain in people with long-term illnesses," in *The Milwaukee Journal Sentinel*, April 5, 2000.

*"Study: Narcotic abuse may be overstated," in *Wisconsin Week*, April 5, 2000.

*"Less pain means gain for medical treatment," in *The Daily Oklahoman*, April 11, 2000.

*"Silent suffering," in *TIME Magazine*, April 17, 2000.

*"Study shows lower rates of opioid abuse," in *The Badger Herald*, April 18, 2000.

*"Timely tidbits for April," in *Media Tactics*, April/May 2000.

*"Increasing use of opioid analgesics has not exacerbated addiction," in *The Brown University Digest of Addiction Theory and Application*, May 2000.

*"Study: More Patients Resorting to Alternative Therapies," in the *Dayton Daily News*, May 9, 2000.

*"As pain medication use increases, abuse remains low," in *Medical Directions*, Summer 2000.

*"Literature abstracts," in *The Network News*, Summer 2000.

*"Opioid analgesia: Medication use not linked to drug abuse," in the *APhA Drug Info Line*, June 2000.

*"Pain treatment and drug abuse, apparently unconnected," in *The New York Times*, July 18, 2000.

Radio Coverage

AMA Radio, April 5, 2000.

World Wide Web Coverage

*"Benefits from opioids outweigh risks, study says," www.cnn.com.

*"Drugs for pain management don't lead to abuse," www.jointogether.org.

*"Examining opioid use: New hope for terminally ill patients," www.lastacts.org.

*"Good news on opioids: Use is up, abuse is down," *https://webmd-practice.medcast.com.*

*"Increase in opioid analgesia does not necessarily mean increase in abuse," *www.pslgroup.com.* (listserve).

*"Increase in opioid analgesia does not necessarily mean increase in abuse," pain_chem_dep@peach.ease.lsoft.com (listserve).

*"Increase in opioid analgesic use doesn't necessarily equate to increase in abuse," www.lastacts.org.

*"More opioid use for pain control does not increase drug abuse," *https://webmd-practice.medcast.com.*

*"Narcotic pain killers don't raise risk of drug abuse: Prescriptions went up, drug abuse went down," *www.webmd.com.*

*"Opioid use up but abuse waning: Wider availability does not lead to overuse, study finds," *www.healthscout.com.*

*"Pain meds do not increase drug abuse," *www.soundpartners.org.*

*"Study shows greater morphine-like prescriptions not causing greater abuse," *www.wrn.com.*

*"Study shows that abuse of narcotics remains low as medical use increases," *www.lastacts.org.*

THE
ROBERT WOOD
JOHNSON
FOUNDATION

1/4
EOL
JMS
RG

November 6, 2000

Mary C. Koscielniak
Accountant
Graduate School, Research and Sponsored Programs
University of Wisconsin-Madison
400 A.W. Peterson Building
750 University Avenue
Madison, WI 53706-1490

Reference: I.D. #036509 - Transmittal of Next Payment

Dear Ms. Koscielniak:

This is in reference to your Robert Wood Johnson Foundation grant in support of the Targeted End-of-Life Projects Initiative: a project to assess states' pain policies.

In reviewing your recent financial report, we note that cumulative expenditures as of July 31, 2000, have been $404,551. The Foundation has made payments to date totaling $407,625 leaving you a cash balance as of July 31, 2000, of $3,074. Enclosed with this letter is our check for $168,873. This check equals your next payment less your cash balance. Also enclosed is your financial reporting form for your use when reporting expenditures.

If I can assist you further, please contact me at 609-243-5844.

Sincerely,

Sophia Kounelias
Financial Analyst

/SXK
Enclosures

cc: David E. Joranson, M.S.S.W.
Rosemary Gibson
Robert C. Andresen

FINANCIAL REPORT
The Robert Wood Johnson Foundation
P.O.Box 2316
Princeton, NJ 08543-2316
Phone:(609)452-8701 Fax:(609)452-9564

FA: SXK **PA:** JMS **PO:** RG

Project Director: David E. Joranson (608-263-7662)
Fiscal Officer : Robert C. Andresen (608/262-2896)

Grantee: *University of Wisconsin-Madison Medical School*
Grant Number: 036509 for [EOL]
Budget Period: Aug-01-2000 to Jul-31-2001
Grant Period: Aug-01-1999 to Jan-31-2002

Budget for Year : 2
Revised:

EXPENDITURES

Item	Approved Budget Amount	Period 1 08/00-01/01	Period 2 02/01-07/01	Period 3	Period 4	Period 5	Period 6	Total	Variance	Pct
PERSONNEL										
Project Director	46,104									
Co-Director	21,189									
Project Advisor	5,718									
Project Analyst	17,288									
Res. Program Manager	24,022									
Info. Processing Cons	18,833									
Assoc Rsch Spec	12,921									
Outreach Specialist	16,960									
Program Assistant	11,252									
Office Assistant	5,292									
Fringe Benefits	60,372									
Personnel Subtotal	239,951									
OTHER DIRECT COSTS										
Supplies	2,700									
Computer Supplies	500									
Duplicating/Printing	2,865									
Telephone	2,155									
Postage	1,500									
Service Agreements(s)	3,000									
Software	6,500									
Travel	15,960									
Other Direct Subtotal	35,180									
INDIRECT COSTS	24,762									

FA: SXK **PA:** JMS **PO:** RG

Project Director: David E. Joranson (608-263-7662)
Fiscal Officer : Robert C. Andresen (608/262-2896)

Grantee: *University of Wisconsin-Madison Medical School*
Grant Number: 036509 for [EOL]
Budget Period: Aug-01-2000 to Jul-31-2001
Grant Period: Aug-01-1999 to Jan-31-2002

Budget for Year : 2
Revised:

EXPENDITURES

Item	Approved Budget Amount	Period 1 08/00-01/01	Period 2 02/01-07/01	Period 3	Period 4	Period 5	Period 6	Total	Variance	Pct
CONSULTANT/CONTRACTUAL	44,000									
Cons/Contrct Subtotal	44,000									
Grand Total	343,893									

University of Wisconsin-Madison
Graduate School, Research and Sponsored Programs

October 25, 2000

Sophia Kounelias
Financial Analyst
The Robert Wood Johnson Foundation
Route 1 and College Road East
P. O. Box 2316
Princeton, NJ 08543-2316

In reply, please refer to
UW Acct No. 133-CW36

RE: Grant #036509

Dear Ms. Kounelias:

Enclosed is the annual financial report for Year 1 on the above-referenced grant for the period February 1, 2000 through July 31, 2000 under the direction of David E. Joranson.

Thank you for your support of this project. If you have any questions regarding this report, please contact me at 608/262-9028.

Sincerely,

Mary C. Koscielniak

Mary C. Koscielniak
Accountant

Enclosure
Cc: Joranson, David E – Med Schl Pain Study
Willians, Carolyn M – Med Schl Pain Study
Medical School Fiscal Services
File

400 A.W. Peterson Building
750 University Avenue
Madison, WI 53706-1490

Telephone (608) 262-3822
Fax (608) 262-5111

FINANCIAL REPORT
The Robert Wood Johnson Foundation
P.O. Box 2316
Princeton, NJ 08543-2316
Phone: (609) 452-8701 Fax: (609) 452-9564

UW Account #133-CW36

FA: MLH PA: LLM PO: RG
Project Director: David E. Joranson (608-263-7662)
Fiscal Officer: Robert C. Andresen (608-262-2896)

Grantee: **University of Wisconsin-Madison**
Grant Number: 036509 for (EOL)
Budget Period: Aug-01-1999 to July-31-2000
Grant Period: Aug-01-1999 to Jan-31-2002

Budget for Year: 1
Revised:

Item	Approved Budget Amount	EXPENDITURES Period 1 08/99-01/00	Period 2 02/00-07/00	Total	Variance
PERSONNEL					
Project Director	78,290.00	36,929.28	41,045.92	77,975.20	314.80
Co-Director	35,981.00	16,972.20	20,118.23	37,090.43	(1,109.43)
Project Advisor	5,395.00	-	5,432.55	5,432.55	(37.55)
Project Analyst	29,357.00	13,847.88	16,431.52	30,279.40	(922.40)
Res Program Manager	33,994.00	15,969.06	17,784.31	33,753.37	240.63
Info Processing Cons	31,980.00	15,084.90	16,818.55	31,903.45	76.55
Assoc Rsch Spec	24,380.00	11,500.02	12,481.98	23,982.00	398.00
Outreach Specialist	16,000.00	2,333.34	16,906.12	19,239.46	(3,239.46)
Program Assistant	10,615.00	-		-	10,615.00
Office Assistant	4,992.00	1,490.30	2,707.10	4,197.40	794.60
Fringe Benefits	91,489.00	35,517.84	46,595.96	82,113.80	9,375.20
Personnel Subtotal	362,473.00	149,644.82	196,322.24	345,967.06	16,505.94
OTHER DIRECT COSTS					
Supplies	2,700.00	1,106.21	3,891.33	4,997.54	(2,297.54)
Computer Supplies	500.00	173.53	599.64	773.17	(273.17)
Duplicating/Printing	2,865.00	53.72	673.86	727.58	2,137.42
Telephone	2,155.00	-	48.89	48.89	2,106.11
Postage	1,500.00	-	447.83	447.83	1,052.17
Service Agreements	3,000.00	694.94	298.00	992.94	2,007.06
Software	6,500.00	2,333.80	4,152.55	6,486.35	13.65
Travel	15,960.00	950.83	9,755.17	10,706.00	5,254.00
Other Direct Subtotal	35,180.00	5,313.03	19,867.27	25,180.30	9,999.70
INDIRECT COSTS	35,789.00	13,946.17	19,457.02	33,403.19	2,385.81
CONSULTANT/CONTRACTUAL					
Cons/Contrct Subtotal	44,000.00	-	-	-	44,000.00
Grand Total	**477,442.00**	**168,904.02**	**235,646.53**	**404,550.55**	**72,891.45**

SXK 11/3/10

Robert C. Andresen, Administrative Officer

P-43071 _ 00116

THE
ROBERT WOOD
JOHNSON
FOUNDATION

April 20, 2001

Robert C. Andresen
Administrative Officer
Graduate School, Research and Sponsored Programs
University of Wisconsin-Madison
750 University Avenue, Room 456
Madison, WI 53706-1490

Reference: I.D. #036509 - Transmittal of Next Payment

Dear Mr. Andresen:

This is in reference to your Robert Wood Johnson Foundation grant in support of the Targeted End-of-Life Projects Initiative: a project to assess states' pain policies.

In reviewing your recent financial report, we note that cumulative expenditures as of January 31, 2001, have been $589,626. The Foundation has made payments to date totaling $576,498 leaving you a cash deficit as of January 31, 2001, of $13,128. Enclosed with this letter is our check for $185,075. This check equals your next payment plus the above mentioned cash deficit. Also enclosed is your financial reporting form for your use when reporting expenditures.

If I can assist you further, please contact me at 609-627-5844.

Sincerely,

Sophia Kounelias
Financial Analyst

/SXK
Enclosures

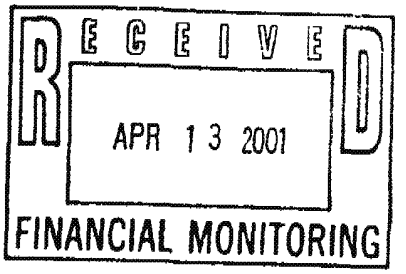
cc: David E. Joranson, M.S.S.W.
Rosemary Gibson

Office of the Vice President and Treasurer

Route 1 and College Road East Post Office Box 2316 Princeton, New Jersey 08543-2316 (609) 452-8701

University of Wisconsin-Madison
Graduate School, Research and Sponsored Programs

April 6, 2001



Sophia Kounelias
Financial Analyst
The Robert Wood Johnson Foundation
Route 1 and College Road East
P. O. Box 2316
Princeton, NJ 08543-2316

In reply, please refer to
UW Acct No. 133-CW36

RE: Grant #036509

Dear Ms. Kounelias:

Enclosed is the interim financial report for Year 2 on the above-referenced grant for the period August 1, 2000 through January 31, 2001 under the direction of David Joranson.

Thank you for your support of this project. If you have any questions regarding this report, please contact me at 608/262-9028.

Sincerely,

Mary C. Koscielniak

Mary C. Koscielniak
Accountant

Enclosure
Cc: Joranson, David – Med Schl Pain Study
Williams, Carolyn - Med Schl Pain Study
Medical School Fiscal Services
File

400 A.W. Peterson Building
750 University Avenue
Madison, WI 53706-1490

Telephone (608) 262-3822
Fax (608) 262-5111

FINANCIAL REPORT
The Robert Wood Johnson Foundation
P.O. Box 2316
Princeton, NJ 08543-2316
Phone: (609) 452-8701 Fax: (609) 452-9564

UW Account #133-CW36

FA: SXK PA: JMS PO: RG
Project Director: David E. Joranson (608-263-7662)
Fiscal Officer: Robert C. Andresen (608-262-2696)

Grantee: **University of Wisconsin-Madison**
Grant Number: 036509 for (EOL)
Budget Period: Aug-01-2000 to July-31-2001
Grant Period: Aug-01-1999 to Jan-31-2002

Budget for Year: 2
Revised:

Item	Approved Budget Amount	Period 1 8/00-01/01	Period 2 02/01-07/01	Total	Variance
		EXPENDITURES			
PERSONNEL					
Project Director	46,104.00	22,710.78		22,710.78	23,393.22
Co-Director	21,189.00	13,809.36		13,809.36	7,379.64
Project Advisor	5,718.00	2,925.00		2,925.00	2,793.00
Project Analyst	17,288.00	9,398.76		9,398.76	7,889.24
Res Program Manager	24,022.00	11,808.00		11,808.00	12,214.00
Info Processing Cons	18,833.00	9,305.52		9,305.52	9,527.48
Assoc Rsch Spec	12,921.00	9,618.00		9,618.00	3,303.00
Outreach Specialist	16,960.00	7,417.26		7,417.26	9,542.74
Program Assistant	11,252.00	2,927.98		2,927.98	8,324.02
Office Assistant	5,292.00	3,812.02		3,812.02	1,479.98
Fringe Benefits	60,372.00	29,632.78		29,632.78	30,739.22
Personnel Subtotal	239,951.00	123,365.46	-	123,365.46	116,585.54
OTHER DIRECT COSTS					
Supplies	2,700.00	3,407.03		3,407.03	(707.03)
Computer Supplies	500.00	295.12		295.12	204.88
Duplicating/Printing	2,865.00	10.00		10.00	2,855.00
Telephone	2,155.00	3,139.03		3,139.03	(984.03)
Postage	1,500.00	1,459.76		1,459.76	40.24
Service Agreements	3,000.00	1,481.82		1,481.82	1,518.18
Software	6,500.00	4,264.01		4,264.01	2,235.99
Travel	15,960.00	18,337.86		18,337.86	(2,377.86)
Other Direct Subtotal	35,180.00	32,394.63	-	32,394.63	2,785.37
INDIRECT COSTS	24,762.00	14,018.41		14,018.41	10,743.59
CONSULTANT/CONTRACTUAL					
Cons/Contrct Subtotal	44,000.00	15,295.50	-	15,295.50	28,704.50
Grand Total	**343,893.00**	**185,074.00**	✓ SXK 4/19/01	**185,074.00**	**158,819.00**

Robert C. Andresen
Robert C. Andresen, Administrative Officer

P-43071 _ 00119

THE
ROBERT WOOD
JOHNSON
FOUNDATION

1/4

~~RG~~ EOL
JMS

October 18, 2001

Robert C. Andresen
Administrative Officer
Graduate School, Research and Sponsored Programs
University of Wisconsin-Madison
750 University Avenue, Room 456
Madison, WI 53706-1490

Reference: I.D. #036509 - Acceptance of Annual Financial Report /
No Payment/Annual Grant Report Requested

Dear Mr. Andresen:

This is in reference to your Robert Wood Johnson Foundation grant in support of the Targeted End-of-Life Projects Initiative: a project to assess states' pain policies.

In reviewing your annual financial report, we note that you have overexpended the approved budget category "Other Direct Subtotal" by more than 5 percent. Please submit a letter which explains this overexpenditure.

Cumulative expenditures as of July 31, 2001, have been $758,263. The Foundation has made payments to date totaling $761,573 leaving you a cash balance of $3,310. We will forward your next payment when your annual grant report is received. Enclosed for your convenience is a copy of your financial reporting form for the period August 1, 2001, through January 31, 2002, reflecting your approved budget of $176,665. Please use this form when reporting expenditures.

We look forward to receiving your annual grant report by October 31, 2001. If I can assist you further, please contact me at 609-627-5844.

Sincerely,

Sophia Kounelias
Financial Analyst

/SXK
Enclosure

cc: David E. Joranson, M.S.S.W.
Rosemary Gibson ✓

FINANCIAL REPORT
The Robert Wood Johnson Foundation
P.O.Box 2316
Princeton, NJ 08543-2316
Phone:(609)452-8701 Fax:(609)627-6416

FA: SXK **PA:** JMS **PO:** RG

Grantee: ***University of Wisconsin-Madison Medical School***

Project Director: David E. Joranson (608-263-7662)
Fiscal Officer : Robert C. Andresen (608-262-0152)

Grant Number: **036509** for **[EOL]**
Budget Period: Aug-01-2001 to Jan-31-2002
Grant Period: Aug-01-1999 to Jan-31-2002

Budget for Year : 3
Revised:

EXPENDITURES

Item	Approved Budget Amount	Period 1 08/01-01/02	Period 2	Period 3	Period 4	Period 5	Period 6	Total	Variance
PERSONNEL									
Project Director	24,435								
Co-Director	11,230								
Project Advisor	3,031								
Project Analyst	9,163								
Res. Program Manager	12,732								
Info. Processing Cons	9,981								
Assoc Rsch Spec	6,848								
Outreach Specialist	8,989								
Program Assistant	5,964								
Office Assistant	2,805								
Fringe Benefits	31,998								
Personnel Subtotal	127,176								
OTHER DIRECT COSTS									
Supplies	933								
Computer Supplies	250								
Duplicating/Printing	2,864								
Telephone	1,077								
Postage	750								
Service Agreements(s)	1,500								
Software	3,250								
Travel	5,700								
Other Direct Subtotal	16,324								
INDIRECT COSTS	12,915								

FINANCIAL REPORT
The Robert Wood Johnson Foundation
P.O.Box 2316
Princeton, NJ 08543-2316
Phone:(609)452-8701 Fax:(609)627-6416

FA: SXK **PA:** JMS **PO:** RG

Grantee: ***University of Wisconsin-Madison Medical School***

Project Director: David E. Joranson (608-263-7662)
Fiscal Officer : Robert C. Andresen (608-262-0152)

Grant Number: **036509** for [**EOL**]
Budget Period: Aug-01-2001 to Jan-31-2002
Grant Period: Aug-01-1999 to Jan-31-2002

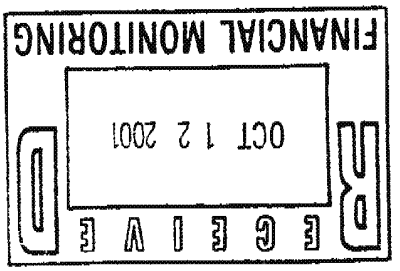
Budget for Year : 3
Revised:

EXPENDITURES

Item	Approved Budget Amount	Period 1 08/01-01/02	Period 2	Period 3	Period 4	Period 5	Period 6	Total	Variance
CONSULTANT/CONTRACTUAL	20,250								
Cons/Contrct Subtotal	20,250								
Grand Total	176,665								

University of Wisconsin-Madison
Graduate School, Research and Sponsored Programs

October 8, 2001



Sophia Kounelias
Financial Analyst
The Robert Wood Johnson Foundation
Route 1 and College Road East
P. O. Box 2316
Princeton, N J 08543-2316

In reply, please refer to
UW Acct No. 133-CW36

RE: Grant # 036509

Dear Ms. Kounelias:

Enclosed is the annual financial report for Year 2 on the above-referenced grant for the period February 1, 2001 through July 31, 2001 under the direction of David E. Joranson, Director of Pain and Policy Studies Group.

Carolyn Williams will submit a letter with their progress report to request a rebudgeting for Year 2 with part of the carryover from year 1. A new budget request for Year 3 will be submitted also.

Thank you for your support of this project. If you have any questions regarding this report, please contact me at 608/262-9028.

Sincerely,

Mary C. Koscielniak

Mary C. Koscielniak
Accountant

Enclosure
Cc: Joranson, David – Med Schl Pain Study
Williams, Carolyn – Med Schl Pain Study
Medical School Fiscal Services
File

400 A.W. Peterson Building
750 University Avenue
Madison, WI 53706-1490

Telephone (608) 262-3822
Fax (608) 262-5111

FINANCIAL REPORT
The Robert Wood Johnson Foundation
P.O. Box 2316
Princeton, NJ 08543-2316
Phone: (609) 452-8701 Fax: (609) 452-9564

UW Account #133-CW36

FA: SXK PA: JMS PO: RG
Project Director: David E. Joranson (608-263-7662)
Fiscal Officer: Robert C. Andresen (608-262-2896)

Grantee: **University of Wisconsin-Madison**
Grant Number: 036509 for (EOL)
Budget Period: Aug-01-2000 to July-31-2001
Grant Period: Aug-01-1999 to Jan-31-2002

Budget for Year: 2
Revised:

Item	Approved Budget Amount	EXPENDITURES Period 1 8/00-01/01	Period 2 02/01-07/01	Total	Variance
PERSONNEL					
Project Director	46,104.00	22,710.78	24,328.06	47,038.84	(934.84)
Co-Director	21,189.00	13,809.36	13,425.76	27,235.12	(6,046.12)
Project Advisor	5,718.00	2,925.00	2,925.00	5,850.00	(132.00)
Project Analyst	17,288.00	9,398.76	9,398.76	18,797.52	(1,509.52)
Res Program Manager	24,022.00	11,808.00	9,840.00	21,648.00	2,374.00
Info Processing Cons	18,833.00	9,305.52	9,305.52	18,611.04	221.96
Assoc Rsch Spec	12,921.00	9,618.00	9,160.00	18,778.00	(5,857.00)
Outreach Specialist	16,960.00	7,417.26	8,241.39	15,658.65	1,301.35
Program Assistant	11,252.00	2,927.98	7,102.16	10,030.14	1,221.86
Office Assistant	5,292.00	3,812.02	3,922.80	7,734.82	(2,442.82)
Fringe Benefits	60,372.00	29,632.78	31,296.09	60,928.87	(556.87)
Personnel Subtotal	239,951.00	123,365.46	128,945.54	252,311.00	(12,360.00)
OTHER DIRECT COSTS					
Supplies	2,700.00	3,407.03	5,775.56	9,182.59	(6,482.59)
Computer Supplies	500.00	295.12	239.20	534.32	(34.32)
Duplicating/Printing	2,865.00	10.00	694.75	704.75	2,160.25
Telephone	2,155.00	3,139.03	1,353.33	4,492.36	(2,337.36)
Postage	1,500.00	1,459.76	976.77	2,436.53	(936.53)
Service Agreements	3,000.00	1,481.82	-	1,481.82	1,518.18
Software	6,500.00	4,264.01	4,244.94	8,508.95	(2,008.95)
Travel	15,960.00	18,337.86	9,049.96	27,387.82	(11,427.82)
Other Direct Subtotal	35,180.00	32,394.63	22,334.51	54,729.14	(19,549.14)
INDIRECT COSTS	24,762.00	14,018.41	13,615.20	27,633.61	(2,871.61)
CONSULTANT/CONTRACTUAL					
Cons/Contrct Subtotal	44,000.00	15,295.50	3,741.40	19,036.90	24,963.10
Grand Total	**343,893.00**	**185,074.00**	**168,636.65**	**353,710.65**	**(9,817.65)**

SXK 10/17/01

Robert C. Andresen

Robert C. Andresen, Administrative Officer

P-43071 _ 00124

THE
ROBERT WOOD
JOHNSON
FOUNDATION

CF
1/4
EOL

November 1, 2001

David E. Joranson, M.S.S.W.
Director
Pain and Policy Studies Group
University of Wisconsin-Madison
406 Science Drive, Suite 202
Madison, WI 53711-1068

CENTRAL FILES
PERMANENT COPY

Reference: I.D. #036509 - Acknowledgement of Annual Progress Report

Dear Mr. Joranson:

This is in reference to your Robert Wood Johnson Foundation grant in support of the Targeted End-of-Life Projects Initiative: a project to assess states' pain policies.

We have received your annual progress report and have forwarded a copy of this report to Rosemary Gibson for her review. If she has any questions or comments, she will contact you directly.

If I can assist you further, please contact me at 609-627-5844.

Sincerely,

Sophia Kounelias MT
Financial Analyst

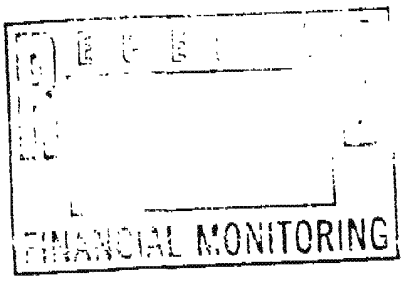
/MT

cc: Robert C. Andresen
Rosemary Gibson

PAIN & POLICY STUDIES GROUP

WHO Collaborating Center
for Policy and Communications
in Cancer Care

October 30, 2001



Sophia Kounelias
Financial Analyst
Robert Wood Johnson Foundation
Route 1 and College Road East
Princeton, NJ 08543-2316

Reference: Grant # 036509

Dear Ms. Kounelias,

Enclosed you will find three copies of the Annual Progress Report, three copies of the Bibliography, and two copies of the Communications Products for the above referenced grant.

Under separate cover, you will be receiving a request to carry over funds and a rebudget for year two and three of this project. If you have any questions, you may contact me directly at 608-263-7371.

Sincerely,

Carolyn M. Williams

Carolyn M. Williams, MBA
Research Program Administrator

UW Comprehensive Cancer Center - University of Wisconsin-Madison Medical School
406 Science Drive, Suite 202 Madison, WI 53711-1068 USA (608) 263-7662 FAX: (608) 263-0259
www.medsch.wisc.edu/painpolicy

PAIN & POLICY STUDIES GROUP

WHO Collaborating Center
for Policy and Communications
in Cancer Care

ANNUAL PROGRESS REPORT
YEAR 2

"BUILDING CAPACITY TO PROMOTE PAIN POLICY THROUGH EVALUATION, RESEARCH AND COMMUNICATION"

TARGETED END-OF-LIFE INITIATIVES

GRANT # 036509
AUGUST 1, 2000 -JULY 31, 2001

SUBMITTED
OCTOBER 31, 2000

PAIN & POLICY STUDIES GROUP
406 SCIENCE DR., SUITE 202
MADISON WI 53711-1068
608.263.7662
PPSG@MED.WISC.EDU

1. WHAT WERE THE PROJECT'S OBJECTIVES AND HOW HAS THE PROJECT MET THEM IN THIS YEAR?

A review of the project's time-line demonstrates that all of the objectives proposed during the second year have been met in a timely fashion.

Part 1: Policy Evaluation

The "Annual Review of New State Pain Policies, 2001" (Annual Review 2001) currently is being prepared that summarizes all new or amended pain policies from the previous year, such as the adoption of intractable pain treatment acts and medical board regulations and guidelines on prescribing controlled substances for pain. The Annual Review 2001 will contain (a) the cumulative trend of pain policies since 1980, and (b) a state-by-state listing, citation, summary, and commentary for each new policy in the previous year.

Although we proposed to complete the Annual Review 2001 by the end of August 2001, we have modified this objective so that it will be completed by the end of December to be able to evaluate all policies adopted in calendar 2001. As a result, the Annual Review will represent a full year, rather than a partial year of policy development. Once completed, the Annual Review will be made available on our website and will be distributed to key individuals and organizations such as health-care providers, patient advocacy groups, state cancer pain initiatives, state government pain commissions, state pain summit meetings and task forces, state legislatures, and medical boards. The first Annual Review was completed in December 2000 and is available on our website at:

www.medsch.wisc.edu/painpolicy/publicat/01ppsgar/contents.htm

We have compared state medical board policies adopted before and after the Federation of State Medical Board's "Model Guidelines for the Use of Controlled Substances for the Treatment of Pain" (Model Guidelines) compare to policies adopted subsequent to the Model Guidelines. The criteria used in "Achieving Balance in Federal and State Pain Policy: A Guide to Evaluation" guided the evaluation for this project. Policy language that met each criterion is being entered into an electronic database. We will analyze the extent that, when compared to "older" policies, "newer" policies contain language that is balanced, recognizing issues such as the medical use of controlled substances, addressing physicians' concerns about investigation, and accurate in the use of terminology. Analyses will be complete by the end of December 2001, and an article that describes the results will be written for publication.

The PPSG continually updates electronic access to a complete database of state pain policies located on its down-loadable website. We obtained state pain policies by using our electronic legal database (Lexis, from "Lexis-Nexis Research Software") and by contacting state agencies. These policies include all relevant federal and state laws, regulations, and guidelines. The accuracy and completeness of this policy database is

assured through our current internal quality-control procedure and our regular monitoring of the policy environment.

Part 2: Empirical Research

PPSG staff updates its database regarding the abuse and medical use of opioid analgesics. Abuse data are collected from the Drug Abuse Warning Network (DAWN) of the Substance Abuse and Mental Health Services Administration (SAMHSA), and medical use data come from the Automation of Reports and Consolidated Orders System (ARCOS) of the Drug Enforcement Administration (DEA). Our previous research with these data demonstrated that the abuse of opioid analgesics was low and stable over time despite a substantial increase in their medical use. This article was published recently in the *Journal of the American Medical Association*. Efforts are being made to monitor these data to evaluate possible significant changes in their trends in recent years.

Part 3: Communications

A major purpose of this grant is to increase awareness of pain policy issues and to support the efforts of individuals and organizations in government and health care to evaluate and improve policies that affect pain management. We proposed to accomplish this goal through several means, including proactive communication of the products from this grant to a broad range of individuals and groups, using means in addition to the ordinary channels of publishing articles in journals. We proposed to: (1) maintain the PPSG website as a source of pain policy information for the public, and (2) provide rapid and efficient technical assistance and dissemination of information. PPSG established a Communications Team to guide efforts to accomplish this objective. More detail is available in our response to Question 5; a summary of the accomplishments follows.

(1) Website: The Team implemented a number of improvements to the website, including a enhanced home-page and site guide, addition of the full text of many new state pain policies, and addition of new links to the site (see Bibliography). Utilization of the site has continued to increase, with approximately 5,800 users per month and a total of about 28,000 hits on our website over the five-month period for which data were available.

(2) Technical assistance and dissemination of information: The PPSG has provided extensive information and assistance to a variety of government and non-government organizations about how to have balanced pain policy, including guidance about how to respond to pain medication abuse and diversion. Such individuals and organizations include the state of Florida division of pharmacy services and the University of Florida, the New Mexico Attorney General, and a joint committee of three national associations, the American Pain Society, the American Society of Addiction Medicine, and the American Academy of Pain Medicine.

(a) Representatives of the U.S. Drug Enforcement Administration contacted the PPSG in March, 2001, to explore the development of a pain forum about the need for a balanced response to the extensive media

attention surrounding OxyContin® in order to prevent states from taking draconian measures to control drug diversion and abuse. Subsequently, the PPSG collaborated with Last Acts and the American Pain Society, in conjunction with Burness Communications, to organize several meetings of an ad hoc pain forum to explore the issues and to develop a joint consensus statement. The consensus statement, which was endorsed by the DEA and 21 health-care and pain organizations, including the American Cancer Society and the American Medical Association, was released at a national press briefing on October 23, 2001.

(b) Following the technical assistance provided to the Michigan Cancer Pain Initiative and the Michigan Commission on End-of-Life Care, Wayne State University sponsored a conference to report the results of the Commission, which made extensive use of information and input from PPSG. David Joranson was invited to present an analysis of the recommendations from the report and how these would improve Michigan policy on end-of-life care compared with the rest of the country.

(c) The PPSG was invited by the American Cancer Society (ACS) to participate in their meeting of the Cancer Pain Management Policy Review Group. The purpose of this meeting was to assist in developing an ACS policy statement in response to the abuse and diversion of pain medications and to ensure that medical practice and patient care are not compromised. The PPSG provided subsequent technical assistance in the drafting of the ACS policy.

(d) Last Acts invited David Joranson to serve as a member of the Provider Education Committee, which is a standing committee of the Last Acts organization.

As interests in pain management and end-of-life care expand, coupled with the substantial media attention surrounding OxyContin® abuse and diversion, requests for our assistance and for providing information sometimes exceed our capacity to respond (and still accomplish our other work under the grant). The recent policy environment relating to pain management and opioid analgesics is becoming increasingly dynamic. Such policy activity involves multi-disciplinary collaboration with various government and non-governmental organizations. We developed an electronic data collection form, as well as a procedure to use it in order to assure we capture the full extent of our technical assistance efforts.

Within the last year, the PPSG Communications Team continued to utilize a strategy for publicizing articles to be published in major journals and other PPSG documents. The strategy consists of two components: (1) to ensure that the article and the electronic notification was clear about the message, and (2) to disseminate this message to our main audiences, including health-care professional groups, government, and the public. As a result of this dissemination strategy, we have received numerous compliments regarding our products and publications.

2. WHAT INTERNAL CHALLENGES WERE ENCOUNTERED DURING THIS YEAR THAT ARE RELATED TO THE PROJECT'S DESIGN, COLLABORATIONS, STAFFING, OPERATIONS, OR OTHER PROJECT FACTORS?

During the last year, we encountered several internal challenges. The Pain & Policy Studies Group (PPSG) was asked to move its office to another location in June 2001. This move necessitated about two weeks of down time because of preparing for the move and subsequent computer network reconfiguration at the new location.

During this time, we transitioned our computer and technical needs from an in-house staff member to a contract for computer information support services. Our decision to contract for an off-site computer network was based on our cost-benefit analysis and necessitated release of the staff member who provided computer and technical support.

After one-and-a-half years of employment, our Communications Specialist, Jessica Nischik, moved away from Madison, WI. We are seeking to employ someone to help us to communicate our work and our message about balanced policy. With the exception of the office move, these changes were unanticipated but have not significantly impacted the PPSG's ability to achieve its goals of policy evaluation, communications, and technical assistance. We have addressed these challenges and believe we are making a successful transition.

3. WHAT CHALLENGES OR SUCCESSES WERE CAUSED BY FACTORS EXTERNAL TO THE PROJECT?

The most significant external challenge encountered by this project was the vast media, professional, and governmental attention to the abuse and diversion of OxyContin®. We experienced an increase in the requests for technical assistance for health-care professionals, regulators, policy makers, and members of the media. In order to more directly address the need for a balanced response, the PPSG engaged directly with the U.S. Drug Enforcement Administration (DEA) to hold a series of meetings to bring together members of national health-care and regulatory organizations. The purpose of the meetings was to develop a joint consensus statement emphasizing the need for a balanced approach to diversion and abuse of opioid pain medications so that efforts to address diversion do not interfere with medical practice and patient care. The joint consensus statement was developed and endorsed by the DEA and 21 professional health-care and pain-related organizations, including the PPSG, the American Medical Association, the American Cancer Society, and the American Pharmaceutical Association. Appointment of DEA Chief Asa Hutchinson delayed the press briefing until October 2001. In addition, PPSG staff members have been frequently requested to make presentations about issues relating to the abuse, diversion, and medical availability of opioid analgesics when treating pain. We have received many requests for updating and publishing information related to the recent medical use and abuse of Schedule II opioid

analgesics. Rather than providing unpublished raw data, and to avoid misinterpretations, efforts are now underway to develop a grant proposal to fund this project, as well as other projects that have become important as a result of escalating concerns about the abuse and diversion of pain medications. This increased demand has strained the resources of our staff, but has given us the opportunity to mediate the potential negative effects of this issue.

The Oxycontin controversy has also resulted in an increase in the interest in and utilization of our products. For example, the frequency of PPSG website hits has continued to increase throughout the last year, and demand for the Evaluation Guide lead to a second printing of 100 copies.

4. IF YOU ARE WORKING IN COLLABORATION WITH OTHER ORGANIZATIONS, OR DEPEND ON OTHER ORGANIZATIONS OR INSTITUTIONS TO MEET THE OBJECTIVES OF THIS PROJECT, HOW ARE THOSE RELATIONSHIPS WORKING?

The PPSG relies on data from two organizations to support our study of medical consumption and abuse of opioid analgesics: the Drug Enforcement Administration (DEA) and the Substance Abuse and Mental Health Services Administration (SAMHSA).

We request the consumption data for individual opioid analgesics directly from the DEA Targeting and Analysis Unit of the Office of Diversion Control, which has been extremely responsive to our various requests. The Unit continues to provide us with both hardcopy and disk-copy of the Automation of Reports and Consolidated Orders System (ARCOS) data on which our analysis of consumption is based. We currently have ARCOS data through the year 2000.

The data for abuse of opioid analgesics come from the Drug Abuse Warning Network (DAWN), which is an annual report of SAMHSA within the U.S. Department of Health and Human Services. As a result of feedback from DAWN users, including the PPSG, staff members at SAMHSA are in the process of re-designing the DAWN report to make it more user-friendly and pharmacologically correct. As a result, the current PPSG in-house database will need to be slightly revised and updated to reflect the changes. Following this, routine data collection and maintenance will be continued. Our ongoing relationship with SAMHSA staff is very good. We routinely request and receive data from SAMHSA that is more detailed than is available on the website reports. As an example of our close collaborative relationship, we were recently advised by our contact that the 2000 Emergency Department data (officially released in August) will be revised, and the final revised version will become available in late 2001 or early 2002. This is a key piece of information as it impacts our internal timeline for drafting and completing the updated article on medical use and abuse of opioid analgesics.

Finally, our collaboration with the American Alliance of Cancer Pain Initiatives (AACPI) continues to be positive and serves as an effective communications channel for our products to the AACPI audience. We have also been please with our collaborations with Last Acts, and Midwest Bioethics and their Community-State Partnerships on End-of-Life Care.

5. WHAT HAVE BEEN THE PROJECT'S KEY COMMUNICATIONS ACTIVITIES DURING THE PAST YEAR?

PPSG Website

The PPSG website has been in service since July 1997. In the past five months[1], the website has averaged 28,178 hits and visits by an average of 5,862 users per month from around the world.

Until June, 2001, the website was maintained by the PPSG's Information Technology Manager. Beginning July, 2001, responsibility for maintaining and expanding the website was assumed by Martha Maurer, Policy Analyst. Maintaining the website involves updating an interactive data-base of policies adopted by state and national boards, legislatures and organizations, adding the new policies as hypertext markup language (HTML) documents, periodically checking website links to insure that they are current and functional, and making any necessary changes to the format of website pages. During this time, PPSG staff met to consider reformatting the "top pages" (see below) of the website. Several modifications were made to increase the format consistency of the pages within the website and to improve the descriptions of our products and instructions to users, all of which will ultimately enhance user navigability. Monthly reports continue to be generated to track the number of website hits and users and to determine the policy documents that are viewed most often by these users. The website e-mail account is also checked weekly for user feedback, which is then either answered by the Policy Analyst that maintains the website, or is directed to the proper PPSG staff member(s).

During the grant period there were nine new policies enacted to address the use of controlled substances for pain management. These policies were adopted by state legislatures, state medical boards, state pharmacy boards, state nursing boards, and national organizations. These policies were obtained by our policy analysts and converted to WordPerfect format either by typing or scanning a hard copy, or converting an already-extant electronic document in another file format. They were then converted to HTML documents, formatted in the style of other PPSG website documents, and then uploaded to our website.

The article, "Pharmacists' Knowledge and Attitudes Towards Opioid Pain Medications in Relation to Federal and State Policy," which was published in the *Journal of the American Pharmaceutical Association*, was made available on the PPSG website in three different formats. The first of these is the full text in Adobe Acrobat PDF format, which users can open and view on their browsers. The second is an interactive PDF version of the document that permits users to view any particular section of the document without having to wait for the entire file to download. The third way is an interactive HTML version of the document that can be viewed using virtually any web browser. This interactive HTML version also permits the viewer to see any part of the document without having to wait for the entire document to download. Additional options that the

[1] Due to a computer problem during the first three months of 2001, we are reporting average website activity using information between April and August, 2001.

viewers have are: download a self-extracting version of the entire document or to submit a request for a free hard copy.

Index of PPSG website "top" pages:

- Home-Page
- About the PPSG
- U.S. Pain Policy Resources
- Data-base of Statutes, Regulations, and Other Governmental Policies
- International Pain Policy Resources
- Bibliography of PPSG Publications
- Related Links
- Glossary

Other Communication Efforts

In addition to the activities relating to the website and technical assistance mentioned under Question 1, the following description provides further information about key activities. Complete information about the communication activities is available in the bibliography.

Pain Forum. The PPSG collaborated with the U.S. Drug Enforcement Administration (DEA) to hold a series of meetings to bring together members of national health-care and regulatory organizations. The purpose of the meetings was to develop a joint consensus statement that emphasizes the need for a balanced approach to diversion and abuse of opioid pain medications so that efforts to address diversion do not interfere with medical practice and patient care. The joint consensus statement was developed and ultimately endorsed by 21 professional health-care and pain-related organizations. Appointment of DEA Chief Asa Hutchinson delayed the press briefing until October 2001.

PPSG Brochure. In cooperation with a graphics design group, the Communications Team developed a brochure describing the PPSG's vision, mission, national and international projects, information about our websites. This brochure has been included in all mailings and continues to be distributed at state, national, and international conferences.

Publicity for the article published in the *Journal of the American Pharmaceutical Association*. We believe that we were successful in reaching our key audiences: We mailed a copy of the article and press release directly to all state medical and pharmacy boards and state medical societies; we notified a large number of individuals and organizations via an e-mail broadcast of the availability of the article on our website; the article and its press release are on our website are frequently accessed by users; there were (and continue to be) numerous placements in media aimed at the public

Publicity for the "Annual Review of State Pain Policies, 2000" Key audiences were successfully targeted in the dissemination of this report: We mailed a printed copy of the document directly to all state legislative librarians, state medical societies, state medical boards, the state cancer pain initiatives in the states with policy changes as well as other key individuals. We notified a large number of individuals and organizations via an e-mail broadcast of the availability of the document on our website. Recipients of this e-mail notification include the Liaison Committee on Pain and Addiction, the Community-State Partnerships on End-of-Life Care, the National Association of Drug Diversion Investigators Prescription Drug Abuse listserve, the OncoPain listserve, the Last Acts Discussion listserve, the State Cancer Pain Initiatives listserve, the Project on Pain Management and Chemical Dependency listserve, and to other professionals interested in pain management policy. This document was also listed in the Last Acts Policy Newsletter, Innovations in End-of-Life Care.

Continued dissemination of "Achieving Balance in Federal & State Pain Policy: A Guide to Evaluation." Due to high demand for this document, 100 reprints were made. There was a second e-mail notification of its availability to academic leaders, pain management advocates, newsletters, professional societies and listserves. In addition, hard copies of this document continue to be requested through the PPSG website.

Presentations at national conferences. PPSG provided presentations on trends and issues in pain policy to participants at a number of conferences sponsored by national organizations. Among these were the Pain Management and Chemical Dependency conference, National Association of Boards of Pharmacy annual meeting, American Alliance of Cancer Pain Initiatives national meeting, American Cancer Society's Pain Management Policy Review Group, National Association of State Controlled Substances Authorities, and American Society of Law Medicine & Ethics meeting. A complete list is included in the bibliography.

6. WHAT ARE THE PROJECT'S OTHER SOURCES OF SUPPORT?

This project has no other sources of support. The other activities of the group are international projects related to our status as the World Health Organization Collaborating Center for Policy and Communications in Cancer Care.

Office space for the Pain & Policy Studies Group (PPSG) and this project is provided by the Medical School of the University of Wisconsin-Madison, the costs of which the PPSG must pay a larger share each year.

7. WHAT ARE YOUR PLANS FOR THE PROJECT NEXT YEAR?

The third year of our grant will involve the continuation of many activities conducted during the second year, as well as those scheduled to end in 2002.

Part 1: Policy Evaluation

We will publish an "Annual Review of New State Pain Policies, 2002" (Annual Review 2002) to demonstrate policy change through to the end of the grant. We will need to monitor the frequency of adoption of new intractable pain treatment policies, as well as regulations and medical board policies that relate to the use of controlled substances for pain. The Annual Review 2002 will be made available on our website and will be distributed to key individuals and organizations such as health-care providers, patient advocacy groups, state cancer pain initiative, state government pain commissions, state pain summit meetings and task forces, state legislatures, and medical boards.

The PPSG will update its electronic database of state pain policies, including the most recent relevant federal and state laws, regulations, and other governmental policies.

We will complete the second of two proposed evaluations of medical board pain guidelines. This second analysis will compare Federation of State Medical Board's "Model Guidelines for the Use of Controlled Substances for the Treatment of Pain" (Model Guidelines) to those policies adopted by state medical boards subsequent to the Model Guidelines. An effort will be made to evaluate the extent that, when compared to the Model Guidelines, "newer" policies contain language that is balanced in recognizing the medical use of controlled substances, is more direct in addressing physicians' concerns about investigation, and is more accurate in the use of terminology.

We will also publish a report to describe changes in federal and state medical, pharmacy, and controlled substances policy that have been adopted prior to the end of January 2002.

Part 2: Empirical Research

PPSG staff will further update its database with the most recent data regarding the abuse and medical use of opioid analgesics. Abuse data will be collected from the Drug Abuse Warning Network (DAWN) of the Substance Abuse and Mental Health Services Administration (SAMSHA), and medical use data will come from the Automation of Reports and Consolidated Orders System (ARCOS) of the Drug Enforcement Administration (DEA). We will monitor these data to evaluate possible significant changes in their trends in recent years.

Part 3: Communications

The Communications Team plans a number of activities to improve the visibility and understanding of the work done by the PPSG. The PPSG will continue to collaborate with a senior communications consultant, Ms. Renie Schapiro, to assist in the development of its communications strategy. We will designate the staff member who replaces Ms. Jessica Nischik as Communications Coordinator. This person will continue

to coordinate our communication and dissemination activities and will serve as a member of our policy evaluation team.

PPSG will disseminate the second "Annual Review of State Pain Policies, 2001" to a wide audience of individuals and organizations in government and health care. We will mail a printed copy of the document directly to all state legislative librarians, state medical societies, state medical boards, the state cancer pain initiatives in the states with policy changes, as well as other key individuals. We will notify a large number of individuals and organizations via an e-mail broadcast of the availability of the document on our website. Recipients of this e-mail notification will include the Liaison Committee on Pain and Addiction, the Community-State Partnerships on End-of-Life Care, as well as the National Association of Drug Diversion Investigators Prescription Drug Abuse listserve, the OncoPain listserve, the Last Acts Discussion listserve, American Alliance of State Cancer Pain Initiatives listserve, the Project on Pain Management and Chemical Dependency listserve, and to other professionals interested in pain management policy.

The Communications team is planning dissemination strategies for each of the articles it will publish in the coming year. These strategies will ensure that the message is clear, and will make use of press coverage, targeted mailings, e-mail broadcast notification, website placement and possible national news coverage. The articles include:

Gilson AM, Joranson DE. "U.S. Policies Relevant to the Prescribing of Opioid Analgesics for the Treatment of Pain in Patients with Addictive Disease." *Clinical Journal of Pain* (in review).

Gilson AM, Joranson DE, Maurer MA, Ryan KR. A Comparative Analysis of State Medical Board Policies Relating to the Use of Controlled Substances for the Treatment of Pain." *journal not yet specified.*

Joranson DE, Carrow GM, Ryan KM, Schaefer L, Gilson AM, Good P, Eadie J, Peine S, Dahl JL. "Pain Management and Prescription Monitoring." *Journal of Pain and Symptom Management* (in press).

Joranson DE, Gilson AM. "Federal and State Policy Issues in the Use of Opioids for Treatment of Pain in Patients who Abuse Controlled Substances." *Principles of Addiction Medicine (Third Edition).*

Joranson DE, Gilson AM, Dahl JL, Haddox JD. "Pain Management, Controlled Substances, and State Medical Policy: A Decade of Change." *Journal of Pain and Symptom Management* (in press).

8. How do you assess the NPO's role in your grant?

We appreciate the Robert Wood Johnson Foundation's support of this project and the very natural flow of information and expression of ideas and issues between the staff members of the PPSG and the staff of RWJ. The *Last Acts* program and the Midwest Bioethics Center has been very helpful in providing input and with the dissemination of information. We especially appreciate working with *Last Acts* and Partnerships in Caring to organize the meeting to bring together the regulatory and pain management communities.

9. How long have you served as project director?

David E. Joranson, MSSW has served as the Director of the Pain & Policy Studies Group since it's inception in 1996. He has served as director of this project for the life of the proposal.

PAIN & POLICY STUDIES GROUP

WHO Collaborating Center
for Policy and Communications
in Cancer Care

ANNUAL PROGRESS REPORT BIBLIOGRAPHY
YEAR 2

"BUILDING CAPACITY TO PROMOTE PAIN POLICY THROUGH EVALUATION, RESEARCH AND COMMUNICATION"

TARGETED END-OF-LIFE INITIATIVES

GRANT # 036509
AUGUST 1, 2000 -JULY 31, 2001

SUBMITTED
OCTOBER 31, 2000

PAIN & POLICY STUDIES GROUP
406 SCIENCE DR., SUITE 202
MADISON WI 53711-1068
608.263.7662
PPSG@MED.WISC.EDU

BIBLIOGRAPHY

Books and Reports

Joranson DE, Gilson AM, Ryan KM, Maurer MA, Nischik JA, Nelson JM. *Achieving Balance in Federal and State Pain Policy: A Guide to Evaluation.* Madison, Wisconsin: Pain and Policy Studies Group, University of Wisconsin Comprehensive Cancer Center, 2000. Also available on our website www.medsch.wisc.edu/painpolicy

* Joranson DE, Maurer MA, Gilson AM, Ryan KM, Nischik JA. *Annual Review of State Pain Policies, 2000.* Madison Wisconsin: Pain & Policy Studies Group, University of Wisconsin Comprehensive Cancer Center; 2001. 500 copies printed and 250 disseminated to date. Also available on our website at www.medsch.wisc.edu/painpolicy

* Joranson DE, Gilson AM. "Federal and State Policy Issues in the Use of Opioids for Treatment of Pain in Patients who Abuse Controlled Substances." In *Principals of Addiction Medicine* (Third Edition) Editor Bonnie B. Wilford. Forthcoming.

Articles

* Dahl JL, Joranson DE, Stein W. "Pain management standards: Their role in improving the quality of care." *Annals of Long-Term Care.* Aug: 9 (8): 25-26, 2001.

* Gilson AM, Joranson DE. "Controlled Substances and Pain Management: Changes in Knowledge and Attitudes of State Medical Regulators." *Journal of Pain and Symptom Management.* (3): 227-37, 2001.

* Gilson AM, Joranson DE, Ryan KM. "Medical Use and Abuse of Opioids (editorial)". *Journal of Pharmaceutical Care in Pain & Symptom Control.* 8(4): 1-4, 2000.

Joranson DJ, Ryan KM, Gilson AM, Dahl JL. "Trends in Medical Use and Abuse of Opioid Analgesics." *Journal of the American Medical Association.* 282 (April 5): 1710-1714, 2000.

*Joranson DJ, Ryan KM, Gilson AM, Dahl JL. "Letter to the Editor: In Reply to 'Reporting Drug Abuse in the Emergency Department.'" *Journal of the American Medical Association.* 284 (August 2): 564, 2000.

*Joranson DE, Berger JW. "Regulatory Issues in Pain Management." *Journal of the American Pharmaceutical Association.* 40 (5, Suppl 1): S60-61, 2000.

* Joranson DE, Gilson, AM. "Pharmacists' Knowledge and Attitudes About Opioid Pain Medications in Relation to Federal and State Policy." *Journal of the American Pharmaceutical Association.* 41(2): 213-220, 2001.

* Joranson DE, Gilson, AM. "Pharmacists' Knowledge and Attitudes About Opioid Pain Medications in Relation to Federal and State Policy." *Journal of the Pharmacy Society of Wisconsin* (May/June 2001) pp 4-10. (published previously in J Am Pharm Assoc. 2001;41: 213-20)

*Joranson DE, Nischik JA. "The Pain & Policy Studies Group: Past, Present, and Future" *Forum- North Carolina Medical Board.* No 2, p 9, 2001.

*Joranson DE. "Improving Pain Policy in the United States and the World" *Update – Pharmaceutical Distribution and Marketing Audits, Inc.* Volume 8, Issue 2, p 6, 9, 2001.

*Joranson DE, Gilson AM, Dahl JL, Haddox JD. "Pain Management, Controlled Substances, and State Medical Policy: A Decade of Change." *Journal of Pain and Symptom Management.* Forthcoming (January 2002)

*Joranson DE, Carrow GM, Ryan KM, Schaefer L, Gilson AM, Good P, Eadie J, Peine S, Dahl JL. "Pain Management and Prescription Monitoring." *Journal of Pain and Symptom Management.* Forthcoming (March 2002)

Brochures and Fact Sheets

* *"Definitions related to the Use of Opioids for the Treatment of Pain"*; A concenses document from the American Academy of Pain Medicine, the American Pain Society, and the American Society of Addiction Medicine, 2001.

* "Promoting Pain Relief and Preventing Abuse of Pain Medication: A Critical Balancing Act"; A joint statement from 21 Health Organization and the Drug Enforcement Administration, 2001.

*"Pain & Policy Studies Group: Promoting pain relief through balanced public policy and communications." The Pain & Policy Studies Group, 2001.

Sponsored Workshop

*"Pain, Controlled Substances and Pharmacy in Wisconsin," February 23, 2001, UW Hospital and Clinics. Attended by 6 professors, pharmacists, and leaders of the Pharmacy Society of Wisconsin.

Presentations and Testimony

*Aaron M. Gilson provided a series of presentations entitled "Pain management and drug abuse: Incidence, effects on practice, and possible solutions" to various health-care organizations in Milwaukee, WI between August 2000 and June 2001.

David E. Joranson, "Trends and issues in pain-related policies: laws and state medical board

guidelines," at Contemporary Concepts in Cancer Pain: Tenth Annual Conference of the Pennsylvania Cancer Pain Initiative, Pennsylvania Cancer Pain Initiative, September 23, 1999.

David E. Joranson, "Testimony of David E. Joranson," at the U.S. Senate Hearing on Pain Management and Improving End of Life Care, October 13, 1999, Washington D.C., Requested by Senator Edward Kennedy, October 1, 1999.

David E. Joranson, "Trends and issues in state pain policy," at Health Care and Law in the New Millennium: Patients' Rights at the Forefront, the American Association of Nurse Attorneys, October 22, 1999, Denver, Colorado.

David E. Joranson, "Evaluation of state pain policy: is it balanced?" at Pain Management: Medical, Legal and Ethical Issues, Baystate Health System Office of Continuing Education, November 10, 1999, Holyoke, Massachusetts.

David E. Joranson, "Guidelines, trends and issues in the state pain-related policy," at the 21st Annual Cancer Symposium: Palliative Issues and Supportive Care in the Cancer Patient, Northwest Community Hospital, November 13, 1999, Arlington Heights, Illinois.

David E. Joranson, "Improving Pain Management Strategies," at Technical Consultation for the Life Project, Kansas Community State Partnership, December 14, 1999, Kansas City, Kansas.

David E. Joranson, "Overview of regulatory history," at Chronic Pain: Medical Management and Regulatory Issues, North Broward Hospital District, April 8, 2000, Pompano Beach, Florida.

David E. Joranson, "Controlled substances: opioids for chronic pain and the anxious physician," at the Pain Management Seminar, Purdue Pharma L.P., April 18, 2000, Des Moines, Iowa.

David E. Joranson, "Progress and issues in pain policy," at Continuing Education in Pain Management, VA Hospital, May 4, 2000, Northport, New York.

David E. Joranson, "Developments in national and state policies affecting pain management: national update on policies and legislation," at the 11th National Meeting for State Cancer Pain Initiatives, American Alliance of State Cancer Pain Initiatives, June 16, 2000, Kansas City, Missouri.

David E. Joranson, "Is It Safe to Prescribe Opioids?," at Pain Management for the Primary Care Clinician, American Pain Society, September 15, 2000, Chicago, Illinois.

David E. Joranson, "Regulatory Barriers to Pain Management and National Cancer Center Control Policy," at Roundtable Discussion on Quality of Life for Cancer Survivors, National Cancer Legislation Advisory Committee, October 2 – 3, 2000, Washington, DC.

David E. Joranson, "A Report Card on State Initiatives Involving Pain Management," at the 16th Annual Educational Conference, The National Association of State Controlled Substances

Authorities, October 31 – November 4, 2000, Louisville, Kentucky.

David E. Joranson, served as moderator for Tri-State Pain Summit on Regulatory Issues, Shenandoah Pain Project & *Pain Relief*/USA, Inc., November 6, 2000, Winchester, Virginia.

David E. Joranson, "Pain Management: Risk Assessment and Legal Concerns," at End of Life Decision Making: What Have We Learned Since Cruzan?, American Society of Law, Medicine & Ethics, November 17 – 18, 2000, Kansas City, Missouri.

David E. Joranson, "Practical Issues for Regulators," at the Fourth Conference on Pain Management and Chemical Dependency, December 7 – 9, 2000, Washington, DC.

David E. Joranson, "Opioid Therapy: Medico/Legal Issues," at American Academy of Pain Medicine's 17th Annual Meeting with Comprehensive Review Course, February 15 – 18, 2001, Miami, Florida.

David E. Joranson, "Analgesic Regulatory Affairs," at the 20th Annual Scientific Meeting, American Pain Society, April 19 – 22, 2001, Phoenix, Arizona.

David E. Joranson, served as moderator at Pain Forum Meeting with Drug Enforcement Administration, April 23 – 24, 2001, Chicago, Illinois.

David E. Joranson, "The Last Link in the Chain: Results of a survey of Wisconsin Pharmacists," at Pharmacy Society of Wisconsin Educational Conference, April 27, 2001, Madison, Wisconsin.

David E. Joranson, "Opioids and the Law," at National Association of Boards of Pharmacy 97th Annual Meeting, May 5 – 9, 2001, Seattle, Washington.

David E. Joranson, "Pain Management Standards: Their Role in Improving the Quality of Care," at American Geriatric Society, May 12, 2001, Chicago, Illinois.

David E. Joranson, "Building a Regulatory Agenda in the CPI Movement," at the 12th National Meeting for State Cancer Pain Initiatives, American Alliance of Cancer Pain Initiatives, June 14 – 16, 2001, Madison, Wisconsin.

David E. Joranson, "Stopping Abuse of Pain Medications, A Critical Balancing Act," at Pain Forum II, Drug Enforcement Agency, July 11, 2001, Chicago, Illinois.

David E. Joranson, "Relieve Pain, Prevent Diversion," at American Cancer Society's Cancer Pain Management Policy Review Group, American Cancer Society, July 20, 2001, Washington, DC.

World Wide Web Sites

www.medsch.wisc.edu/painpolicy

Provides full text of individual state pain policies and pain related federal policies, links to other pain organizations, a glossary of terms and full text of articles published by the PPSG. Madison, WI: Pain & Policy Studies Group. Estimated 5,862 visits per month.

Press Kits and News Releases

A news release on the *Journal of the American Medical Association* article "Trends in Medical Use and Abuse of Opioid Analgesics", mailed by JAMA on March 30, 2000 to 1500 reporters nationally. Also accessible to over 2,000 domestic and international journalists through "EurekAlert!" (a Web site for journalists maintained by the American Association for the Advancement of Science).

A news release on the *Journal of the American Medical Association* article "Trends in Medical Use and Abuse of Opioid Analgesics", mailed by the PPSG on April 1, 2000 to 413 state medical societies, state medical boards, state boards of pharmacy, attorney generals, grant advisors, academic leaders and pain management advocates. One hundred sixty-six academic leaders, pain management advocates, newsletters, professional societies and listserves were notified through email.

*An e-mail news release on the *"Annual Review of State Pain Policies 2000"* was broadcasted to 173 academic leaders, pain management advocates, newsletters, professional societies and listserves on March 16, 2001.

*An e-mail news release on *"Achieving Balance in Federal and State Pain Policy: A guide to Evaluation"* was broadcasted to 173 academic leaders, pain management advocates, newsletters, professional societies and listserves on March 16, 2001.

*An e-mail news release on the *Journal of the American Pharmaceutical Association* article "Pharmacists' Knowledge and Attitudes about Opioid Pain Medications in Relation to Federal and State Policy" article was broadcasted to 173 academic leaders, pain management advocates, newsletters, professional societies and listserves on April 3, 2001.

Print Coverage

"States are relaxing rules on painkillers: Improving care at the end of life," in *The States*, May 1999.

"Web Site Offers Pain Management Policy Information," in the *Oregon State Board of Pharmacy Newsletter*, August 1999.

"Can doctors put their fears to rest?" in *Medical Economics,* February 21, 2000.

"Highlight: The Pain & Policy Studies Group (PPSG)," in *ASPMN Pathways*, March/April 2000.

"More opiates used to treat severe pain," in *Reuter's Health Information*, April 4, 2000.

"Abuse of opioid painkillers by patients is uncommon, study finds," in *Oncology Times*, April 5, 2000.

"High use of narcotic painkillers is not linked to abuse," in *The Oregonian*, April 5, 2000.

"Study finds drugs for pain not abused: Results support efforts to manage pain in people with long-term illnesses," in *The Milwaukee Journal Sentinel*, April 5, 2000.

"Study: Narcotic abuse may be overstated," in *Wisconsin Week*, April 5, 2000.

"Less pain means gain for medical treatment," in *The Daily Oklahoman*, April 11, 2000.

"Silent suffering," in *TIME Magazine*, April 17, 2000.

"Study shows lower rates of opioid abuse," in *The Badger Herald*, April 18, 2000.

"Timely tidbits for April," in *Media Tactics*, April/May 2000.

"Increasing use of opioid analgesics has not exacerbated addiction," in *The Brown University Digest of Addiction Theory and Application*, May 2000.

"Study: More Patients Resorting to Alternative Therapies," in the *Dayton Daily News*, May 9, 2000.

"As pain medication use increases, abuse remains low," in *Medical Directions*, Summer 2000.

"Literature abstracts," in *The Network News*, Summer 2000.

"Opioid analgesia: Medication use not linked to drug abuse," in the *APhA Drug Info Line*, June 2000.

"Pain treatment and drug abuse, apparently unconnected," in *The New York Times*, July 18, 2000.

*"Literature abstracts" in *The Network News* (Published by Memorial Sloan-Kettering Cancer Center) Summer 2001, Volume 13

* "Use of Narcotic Pain Medication Remains Low as Medical Use Increases" in *PCS Newsletter: News for Fellows of the Philippine College of Surgeons*, August 2000.

* "Improving Pain Management" in *Prescriber's Letter*, Vol. 7, No. 9 September 2000.

* "Triplicate prescription forms in Maine" in *Bangor Daily News*, September 28, 2000.

* "Patient danger seen in druggist 'conscience' bill" in *The Capital Times*, April 30, 2001.

* "Pain Management Policies: An Evaluation" in *State Health Notes*, Vol. 21, Number 336, November 6, 2000.

* "Drug Diversion and Dependency" in *Journal of the Pharmacy Society of Wisconsin*, Nov/Dec 2000.

* "New Pain Policy Evaluation Guide" in *Your Last Acts Partner Letter*, November-December 2000.

*"Regulatory Update" in *Cancer Pain Forum*, Winter 2000, Issue 2.

* " Treating pain is no simple matter" in *The Milwaukee Journal Sentinel*, January 8, 2001.

* "Spotlight on the Pain & Policy Studies Group" in *The Pain Connection: the Newsletter of the American Pain Foundation*, Spring 2001.

* "Playing with Pain Killers" in *Newsweek*, April 9, 2001.

* "Study Evaluates Pharmacists' Knowledge of Attitudes Toward Pain Medication Dispensing" in *Nation Boards of Pharmacy Newsletter*, July 2001.

* "Program Highlights" in *University of Wisconsin Comprehensive Cancer Center Annual Report 2000-2001.*

* "Champion of Change Dr. June Dahl: Her long fight for national pain management standards comes to fruition" in *Quarterly – The Magazine for University of Wisconsin Medical School Alumni and Friends*, Vol 3, No 2, Spring 2001.

* "Regulatory Attitudes Improve, But Fear of Opioid Use Continues" in *The Quality Indicator: Physician Resource*, April 2001.

Radio Coverage

AMA Radio, April 5, 2000.

World Wide Web Coverage

"Benefits from opioids outweigh risks, study says," *www.cnn.com*.

"Drugs for pain management don't lead to abuse," *www.jointogether.org*.

"Examining opioid use: New hope for terminally ill patients," *www.lastacts.org*.

"Good news on opioids: Use is up, abuse is down," *https://webmd-practice.medcast.com*.

"Increase in opioid analgesia does not necessarily mean increase in abuse," *www.pslgroup.com*. (listserve).

"Increase in opioid analgesia does not necessarily mean increase in abuse," pain_chem_dep@peach.ease.lsoft.com (listserve).

"Increase in opioid analgesic use doesn't necessarily equate to increase in abuse," *www.lastacts.org*.

"More opioid use for pain control does not increase drug abuse," *https://webmd practice.medcast.com*.

"Narcotic pain killers don't raise risk of drug abuse: Prescriptions went up, drug abuse went down," *www.webmd.com*.

"New Guide on Federal and State pain Policy Now Available," *Last Acts Policy Newsletter*, vol 1, issue 6 (email newsletter).

"Opioid use up but abuse waning: Wider availability does not lead to overuse, study finds," *www.healthscout.com*.

"Pain meds do not increase drug abuse," *www.soundpartners.org*.

"Study shows greater morphine-like prescriptions not causing greater abuse," *www.wrn.com*.

"Study shows that abuse of narcotics remains low as medical use increases," *www.lastacts.org*.

* "Nursing home patients' pain underestimated, officials say", in *The Charleston Gazette Online*, www.wvgazette.com.

* " New Guide on Federal and State Pain Policy Now Available" in *Last Acts Policy Newsletter* – Volume 1, Issue 6, September 2000.

* "New Pain Policy Resource Available" in *BoardNet News* (Federation of State Medical Boards online newsletter, October 13, 2000.

* " "PPSG Releases Annual Review of State Pain Policies 2000" in *Last Acts Policy Newsletter*- Volume 2, Issue 2, February 2001.

* "Abuse of powerful pain reliever rising" in *The Round Up New Mexico State U (U-Wire)*, March 15, 2001.

* "PPSG Annual Review of State Pain Policies Available" in *AACPI update*, March 16, 2001 (listserve).

* "PPSG Study Reports on Pharmacists and Pain Policy" in *Last Acts Policy Newsletter*-Volume 2, Issue 4, April 2001.

* "Regulatory Attitudes Improve, But Fear of Opioid Use Continues" in *Premier Healthcare Resource, Inc.*, April 2001.

THE ROBERT WOOD JOHNSON FOUNDATION

April 29, 2002

David E. Joranson, M.S.S.W.
Director
Pain and Policy Studies Group
University of Wisconsin-Madison
406 Science Drive, Suite 202
Madison, WI 53711-1068

Reference: I.D. #036509 - Approval of Extension Request

Dear Mr. Joranson:

This is in reference to your Robert Wood Johnson Foundation grant in support of the Targeted End-of-Life Projects Initiative: a project to assess states' pain policies.

We have reviewed your extension request for the period August 1, 2001, through January 31, 2002, and approve it through April 30, 2002. Enclosed is a copy of your financial reporting form with your approved budget of $176,665 for use when reporting expenditures for the above-mentioned period.

Your final financial and narrative reports are now due May 31, 2002.

Please review your approved budget. If projected expenditures will vary from the current budget, you should submit a budget revision request. Enclosed for your convenience is a copy of our Budget Revision Guidelines.

If I can assist you further, please contact me at 609-627-5844.

Sincerely,

Sophia Kounelias
Financial Analyst

/SXR
Enclosures

cc: Robert C. Andresen
Rosemary Gibson

Office of the Vice President and Treasurer

Route 1 and College Road East Post Office Box 2316 Princeton, New Jersey 08543-2316 (609) 452-8701

PAIN & POLICY STUDIES GROUP

WHO Collaborating Center
for Policy and Communications
in Cancer Care

April 8, 2002

Sophiea Kounelias
Financial Analyst
The Robert Wood Johnson Foundation
Route 1 and College Road East
P.O. Box 2316
Princeton NJ 08543-2316

Reference ID: #036509
UW # 133 CW36

Dear Ms. Kounelias;

We would like to request a grant extension of our project entitled "Building Capacity to Promote Pain Policy Through Evaluation, Research and Communication". The current end-date is January 31, 2002. We would like to extend the end-date to April 30, 2002. The additional three months would allow us to complete the follow-up for a number of research projects and to prepare manuscripts for publication as discussed with Ms. Rosemary Gibson.

As was discussed with Carolyn Williams, Research Program Manager for the project, we will prepare a separate budget and budget narrative for the extension period and forward it to you under separate cover.

Thank you for your assistance with this matter.

Sincerely,

David E. Joranson, Senior Scientist
Director

Debbie Mettyer
Office of Research & Grad. Studies

Robert C. Andresen
Robert C. Andresen, Admin. Officer
Research & Sponsored Programs

cc: Rosemary Gibson
Carolyn Williams
Mary Koscielniak
Sandi Robins

FINANCIAL REPORT
The Robert Wood Johnson Foundation
P.O.Box 2316
Princeton, NJ 08543-2316
Phone:(609)452-8701 Fax:(609)627-6416

FA: SXK **PA:** JMS **PO:** RG

Project Director: David E. Joranson (608-263-7662)
Fiscal Officer : Robert C. Andresen (608-262-2896)

Grantee: ***University of Wisconsin-Madison Medical School***
Grant Number: **036509** for **[EOL]**
Budget Period: Aug-01-2001 to Apr-30-2002
Grant Period: Aug-01-1999 to Apr-30-2002

Budget for Year : 3
Revised: Apr-29-2002

EXPENDITURES

Item	Approved Budget Amount	Period 1 08/01-01/02	Period 2 02/02-04/02	Period 3	Period 4	Period 5	Period 6	Total	Variance	Pct
PERSONNEL										
Project Director	24,435								24,435	0
Co-Director	11,230								11,230	0
Project Advisor	3,031								3,031	0
Project Analyst	9,163								9,163	0
Res. Program Manager	12,732								12,732	0
Info. Processing Cons	9,981								9,981	0
Assoc Rsch Spec	6,848								6,848	0
Outreach Specialist	8,989								8,989	0
Program Assistant	5,964								5,964	0
Office Assistant	2,805								2,805	0
Fringe Benefits	31,998								31,998	0
Personnel Subtotal	127,176								127,176	
OTHER DIRECT COSTS										
Supplies	933								933	0
Computer Supplies	250								250	0
Duplicating/Printing	2,864								2,864	0
Telephone	1,077								1,077	0
Postage	750								750	0
Service Agreements(s)	1,500								1,500	0
Software	3,250								3,250	0
Travel	5,700								5,700	0
Other Direct Subtotal	16,324								16,324	
INDIRECT COSTS	12,915								12,915	0

FINANCIAL REPORT

The Robert Wood Johnson Foundation
P.O.Box 2316
Princeton, NJ 08543-2316
Phone: (609) 452-8701 Fax: (609) 627-6416

FA: SXK **PA:** JMS **PO:** RG

Project Director: David E. Joranson (608-263-7662)
Fiscal Officer : Robert C. Andresen (608-262-2896)

Grantee: *University of Wisconsin-Madison Medical School*
Grant Number: **036509** for [EOL]
Budget Period: Aug-01-2001 to Apr-30-2002
Grant Period: Aug-01-1999 to Apr-30-2002

Budget for Year : 3
Revised: Apr-29-2002

EXPENDITURES

Item	Approved Budget Amount	Period 1 08/01-01/02	Period 2 02/02-04/02	Period 3	Period 4	Period 5	Period 6	Total	Variance	Pct
CONSULTANT/CONTRACTUAL	20,250								20,250	0
Cons/Contrct Subtotal	20,250								20,250	
Grand Total	**176,665**								**176,665**	

THE
ROBERT WOOD
JOHNSON
FOUNDATION

October 8, 2002

Robert C. Andresen
Administrative Officer
Research and Sponsored Programs
University of Wisconsin-Madison
750 University Avenue, 4th Floor
Madison, WI 53706-1490

Reference: I.D. #036509 - Financial Report Received/No Payment

Dear Mr. Andresen:

This is in reference to your Robert Wood Johnson Foundation grant in support of the Targeted End-of-Life Projects Initiative: a project to assess states' pain policies.

In reviewing your recent financial report, we note that you have overexpended the approved budget categories "Other Direct Subtotal" and "Personnel Subtotal" by more than 5 percent. Please submit a letter which explains these overexpenditures.

Also, in reviewing the final status of this grant, we note that a letter of explanation was requested for the overexpenditures on the "Other Direct Subtotal" per our letter dated October 18, 2001. Please submit this outstanding letter of explanation to the Foundation.

Cumulative expenditures as of April 30, 2002, have been $977,073. The Foundation has made payments to date totaling $761,573 leaving you a cash deficit as of April 30, 2002, of $215,500. We will release your final payment once the letters of explanations are received. Please submit these required letters by October 21, 2002.

If I can assist you further, please contact me at 609-627-5844.

Sincerely,

Sophia Kounelias
Financial Analyst

/SXK

cc: David E. Joranson, M.S.S.W.
Rosemary Gibson

Office of the Vice President and Treasurer

Route 1 and College Road East Post Office Box 2316 Princeton, New Jersey 08543-2316 (609) 452-8701

University of Wisconsin-Madison
Graduate School, Research and Sponsored Programs

September 24, 2002

Sophia Kounelias
Financial Analyst
The Robert Wood Johnson Foundation
Route 1 and College Road East
P. O. Box 2316
Princeton, N J 08543-2316

In reply, please refer to
UW Acct No. 133-CW36

RE: Grant # 036509

Dear Ms. Kounelias:

Enclosed is the final financial report for Year 3 on the above-referenced grant for the period February 1, 2002 through April 30, 2002 under the direction of David Joranson in the Pain and Policy Studies Group at the University of Wisconsin-Madison.

Total expenditures for this project were $977,070.35. The total award amount was $998,000.00. The University of Wisconsin has received $761,573.00 from the Robert Wood Johnson Foundation for this grant. Once our final report has been reviewed, would you please release the final payment of $215,497.35.

Thank you for your support of this project. If you have any questions regarding this report, please contact me at 608/262-9028.

Sincerely,

Mary C. Koscielniak

Mary C. Koscielniak
Accountant

Enclosure
Cc: Joranson, David - Med Schl Pain Study
Kline, Janet - Med Schl Pain Study
Medical School Fiscal Services
File

400 A.W. Peterson Building
750 University Avenue
Madison, WI 53706-1490

Telephone (608) 262-3822
Fax (608) 262-5111
Home Page http://www.rsp.wisc.edu

FINANCIAL REPORT
The Robert Wood Johnson Foundation
P.O. Box 2316
Princeton, NJ 08543-2316
Phone: (609) 452-8701 Fax: (609) 452-9564

UW Account #133-CW36

FA: SXK PA: JMS PO: RG
Project Director: David E. Joranson (608-263-7662)
Fiscal Officer: Robert C. Andresen (608-262-2896)

Grantee: **University of Wisconsin-Madison**
Grant Number: 036509 for (EOL)
Budget Period: Aug-01-2001 to Apr-30-2002
Grant Period: Aug-01-1999 to Apr-30-2002

Budget for Year: 3
Revised: Apr-29-2002

EXPENDITURES

Item	Approved Budget Amount	Period 1 8/01 - 1/02	Period 2 2/02 - 4/02	Total	Variance
PERSONNEL					
Project Director	24,435.00	28,300.40	14,075.43	42,375.83	(17,940.83)
Co-Director	11,230.00	11,962.44	6,147.05	18,109.49	(6,879.49)
Project Advisor	3,031.00	3,095.62	-	3,095.62	(64.62)
Project Analyst	9,163.00	9,774.73	4,860.51	14,635.24	(5,472.24)
Res Program Manager	12,732.00	9,845.49	6,103.65	15,949.14	(3,217.14)
Info Processing Cons	9,981.00	5,119.29	-	5,119.29	4,861.71
Assoc Rsch Spec	6,848.00	7,549.49	3,911.25	11,460.74	(4,612.74)
Outreach Specialist	8,989.00	5,625.00	3,375.00	9,000.00	(11.00)
Program Assistant	5,964.00	8,304.92	4,088.58	12,393.50	(6,429.50)
Office Assistant	2,805.00	2,012.76	877.72	2,890.48	(85.48)
Fringe Benefits	31,998.00	29,733.09	14,340.65	44,073.74	(12,075.74)
Personnel Subtotal	127,176.00	121,323.23	57,779.84	179,103.07	(51,927.07)
OTHER DIRECT COSTS					
Supplies	933.00	926.00	-	926.00	7.00
Computer Supplies	250.00	270.00	-	270.00	(20.00)
Duplicating/Printing	2,864.00	2,586.54	-	2,586.54	277.46
Telephone	1,077.00	1,206.71	-	1,206.71	(129.71)
Postage	750.00	750.00	-	750.00	-
Service Agreements	1,500.00	716.25	-	716.25	783.75
Software	3,250.00	3,380.06	2,559.94	5,940.00	(2,690.00)
Travel	5,700.00	7,408.91	-	7,408.91	(1,708.91)
Other Direct Subtotal	16,324.00	17,244.47	2,559.94	19,804.41	(3,480.41)
INDIRECT COSTS	12,915.00	12,471.09	5,430.58	17,901.67	(4,986.67)
CONSULTANT/CONTRACTUAL					
Cons/Contrct Subtotal	20,250.00	-	2,000.00	2,000.00	18,250.00
Grand Total	**176,665.00**	**151,038.79**	**67,770.36**	**218,809.15**	**(42,144.15)**

& Ltr of no expenditure required.

SXK 10/4/02

Robert C. Andresen

Robert C. Andresen, Administrative Officer

P-43071_00155

THE
ROBERT WOOD
JOHNSON
FOUNDATION

September 11, 2002

David E. Joranson, M.S.S.W.
Director
Pain and Policy Studies Group
University of Wisconsin-Madison
406 Science Drive, Suite 202
Madison, WI 53711-1068

Reference: I.D. #036509 - Second Request for Report

Dear Mr. Joranson:

This is in reference to your Robert Wood Johnson Foundation grant in support of the Targeted End-of-Life Projects Initiative: a project to assess states' pain policies.

We have previously requested that you submit your final financial report for the period ended April 30, 2002. To date, we have not received this document.

Please submit the above mentioned report to the attention of Sophia Kounelias by September 25, 2002. If you have already submitted this material, please disregard this request. Your cooperation is appreciated.

Sincerely,

Janice A. Opalski
Director of Financial Monitoring

JAO\sam

cc: Robert C. Andresen
Rosemary Gibson

THE
ROBERT WOOD
JOHNSON
FOUNDATION

July 17, 2002

David E. Joranson, M.S.S.W.
Director
Pain and Policy Studies Group
University of Wisconsin-Madison
406 Science Drive, Suite 202
Madison, WI 53711-1068

Reference: I.D. #036509 - Request for Final Financial Report

Dear Mr. Joranson:

This is in reference to your Robert Wood Johnson Foundation grant in support of the Targeted End-of-Life Projects Initiative: a project to assess states' pain policies.

We have received your final narrative report and have forwarded a copy of this report to Rosemary Gibson for her review. If she has any questions or comments, she will contact you directly.

We look forward to receiving your final financial report by July 30, 2002. If I can assist you further, please contact me at 609-627-5844.

Sincerely,

Sophia Kounelias
Financial Analyst

/SXR

cc: Robert C. Andresen
Rosemary Gibson

Office of the Vice President and Treasurer

Route 1 and College Road East Post Office Box 2316 Princeton, New Jersey 08543-2316 (609) 452-8701

PAIN & POLICY STUDIES GROUP

WHO Collaborating Center
for Policy and Communications
in Cancer Care

July 12, 2002

Sophia Kounelias
Financial Analyst
Robert Wood Johnson Foundation
Route 1 and College Road East
Princeton, NJ 08543-2316

Reference: RWJ Grant # 036509
UW 133-CW36

Dear Ms. Kounelias,

Enclosed please find three copies of the Final Grant Report, three copies of the Bibliography, and two copies of the Communications Products for the above referenced grant.

Sincerely,

Janet Kline

Janet Kline, MLS
Program Administrator

Enclosures

UW Comprehensive Cancer Center - University of Wisconsin-Madison Medical School
406 Science Drive, Suite 202 Madison, WI 53711-1068 USA (608) 263-7662 FAX: (608) 263-0259
www.medsch.wisc.edu/painpolicy

FINAL GRANT REPORT

"BUILDING CAPACITY TO PROMOTE PAIN POLICY THROUGH EVALUATION, RESEARCH AND COMMUNICATION"

TARGETED END-OF-LIFE INITIATIVES

GRANT # 036509
AUGUST 1, 1999 -DECEMBER 31, 2001
(EXTENDED TO APRIL 30, 2002)

SUBMITTED
JULY 12, 2002

PAIN & POLICY STUDIES GROUP
406 SCIENCE DR., SUITE 202
MADISON WI 53711-1068
608.263.7662
PPSG@MED.WISC.EDU

1. WHAT WERE THE PROJECT'S OBJECTIVES AND TO WHAT EXTENT HAS THE PROJECT MET THESE OBJECTIVES?

A review of the project's time-line demonstrates that all objectives proposed during the grant have been met in a timely fashion.

Part 1: Policy Evaluation

(1) Guide to Evaluation of Federal and State Policies. We completed the document "Achieving Balance in Federal and State Pain Policy: A Guide to Evaluation" in July 2000, which presents the results of the first systematic evaluation of pain-related policies from the federal government and the 50 states. All policies that were in force and available through March 2000 were examined using a set of well-documented criteria based on a Central Principle that should underlie all pain policy. The document is designed as a workbook to assist professionals and groups who want to learn how to evaluate policies that can affect pain management in their state or at the federal level.

The document has been prepared in a hard-copy format and was disseminated to all Robert Wood Johnson Foundation (RWJF)-supported Community-State Partnerships, other grantees including Last Acts, and to State Cancer Pain Initiatives, State Medical Societies and many other organizations. The document also was prepared in an electronic format and placed on the PPSG website. We automated the policy matrix so that clicking the dot in a cell, which represents an identified policy, links the user directly to a down-loadable electronic document with the full text of the policy, citation, the relevant criteria, a comment, and a link to a more complete discussion of the criteria. The document was made available on CD-ROM for organizations or individuals who made this request. Detail about our dissemination of the Evaluation Guide is available in Question 5.

(2) Changes in Federal and State Policy: 1998-2001. After a careful review of this project we decided that, rather than creating a separate document, this information should be included in the "Annual Review of New State Pain Policies, 2001," which is discussed below.

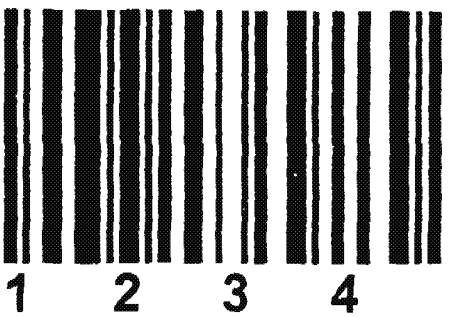
(3) Annual Reviews of New State Pain Policies. We prepared an "Annual Review of New State Pain Policies, 2000" (Annual Review 2000) and an "Annual Review of New State Pain Policies, 2001" (Annual Review 2001), summarizing all new or amended pain policies from 2000 and 2001, such as the adoption of new intractable pain treatment acts and medical board regulations and guidelines on prescribing controlled substances for pain. Both Annual Reviews contained (a) the cumulative trend of pain policies since 1980, and (b) a state-by-state listing, citation, summary, and commentary for each new policy in the previous year.

Although we proposed to complete each Annual Review by the end of August of that year, we modified this objective so that the reports would be completed by the end of December to be able to evaluate and report on all policies adopted during the calendar

SECTION

9

FINAL NARRATIVE & FINANCIAL REPORTS



THE
ROBERT WOOD
JOHNSON
FOUNDATION

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KG
EOL

April 29, 2002

David E. Joranson, M.S.S.W.
Director
Pain and Policy Studies Group
University of Wisconsin-Madison
406 Science Drive, Suite 202
Madison, WI 53711-1068

Reference: I.D. #036509 - Approval of Extension Request

Dear Mr. Joranson:

This is in reference to your Robert Wood Johnson Foundation grant in support of the Targeted End-of-Life Projects Initiative: a project to assess states' pain policies.

We have reviewed your extension request for the period August 1, 2001, through January 31, 2002, and approve it through April 30, 2002. Enclosed is a copy of your financial reporting form with your approved budget of $176,665 for use when reporting expenditures for the above-mentioned period.

Your final financial and narrative reports are now due May 31, 2002.

Please review your approved budget. If projected expenditures will vary from the current budget, you should submit a budget revision request. Enclosed for your convenience is a copy of our Budget Revision Guidelines.

If I can assist you further, please contact me at 609-627-5844.

Sincerely,

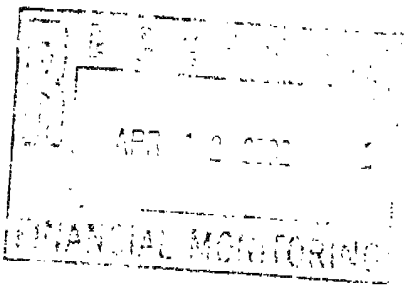
Sophia Kounelias
Financial Analyst

/SXR
Enclosures

cc: Robert C. Andresen
Rosemary Gibson

PAIN & POLICY STUDIES GROUP

WHO Collaborating Center
for Policy and Communications
in Cancer Care



April 8, 2002

Sophiea Kounelias
Financial Analyst
The Robert Wood Johnson Foundation
Route 1 and College Road East
P.O. Box 2316
Princeton NJ 08543-2316

Reference ID: #036509
UW # 133 CW36

Dear Ms. Kounelias;

We would like to request a grant extension of our project entitled "Building Capacity to Promote Pain Policy Through Evaluation, Research and Communication". The current end-date is January 31, 2002. We would like to extend the end-date to April 30, 2002. The additional three months would allow us to complete the follow-up for a number of research projects and to prepare manuscripts for publication as discussed with Ms. Rosemary Gibson.

As was discussed with Carolyn Williams, Research Program Manager for the project, we will prepare a separate budget and budget narrative for the extension period and forward it to you under separate cover.

Thank you for your assistance with this matter.

Sincerely,

David E. Joranson, Senior Scientist
Director

Office of Research & Fund. Studies

Robert C. Andresen, Admin. Officer
Research & Sponsored Programs

cc: Rosemary Gibson
Carolyn Williams
Mary Koscielniak
Sandi Robins

UW Comprehensive Cancer Center - University of Wisconsin-Madison Medical School
406 Science Drive, Suite 202 Madison, WI 53711-1068 USA (608) 263-7662 FAX: (608) 263-0259
www.medsch.wisc.edu/painpolicy

FINANCIAL REPORT
The Robert Wood Johnson Foundation
P.O.Box 2316
Princeton, NJ 08543-2316
Phone:(609)452-8701 Fax:(609)627-6416

FA: SXK **PA:** JMS **PO:** RG

Project Director: David E. Joranson (608-263-7662)
Fiscal Officer : Robert C. Andresen (608-262-2896)

Grantee: ***University of Wisconsin-Madison Medical School***
Grant Number: **036509** for [EOL]
Budget Period: Aug-01-2001 to Apr-30-2002
Grant Period: Aug-01-1999 to Apr-30-2002

Budget for Year : 3
Revised: Apr-29-2002

EXPENDITURES

Item	Approved Budget Amount	Period 1 08/01-01/02	Period 2 02/02-04/02	Period 3	Period 4	Period 5	Period 6	Total	Variance	Pct
PERSONNEL										
Project Director	24,435									
Co-Director	11,230									
Project Advisor	3,031									
Project Analyst	9,163									
Res. Program Manager	12,732									
Info. Processing Cons	9,981									
Assoc Rsch Spec	6,848									
Outreach Specialist	8,989									
Program Assistant	5,964									
Office Assistant	2,805									
Fringe Benefits	31,998									
Personnel Subtotal	127,176									
OTHER DIRECT COSTS										
Supplies	933									
Computer Supplies	250									
Duplicating/Printing	2,864									
Telephone	1,077									
Postage	750									
Service Agreements(s)	1,500									
Software	3,250									
Travel	5,700									
Other Direct Subtotal	16,324									
INDIRECT COSTS	12,915									

FINANCIAL REPORT
The Robert Wood Johnson Foundation
P.O.Box 2316
Princeton, NJ 08543-2316
Phone:(609)452-8701 Fax:(609)627-6416

FA: SXK **PA:** JMS **PO:** RG

Project Director: David E. Joranson (608-263-7662)
Fiscal Officer : Robert C. Andresen (608-262-2896)

Grantee: ***University of Wisconsin-Madison Medical School***
Grant Number: 036509 for [EOL]
Budget Period: Aug-01-2001 to Apr-30-2002
Grant Period: Aug-01-1999 to Apr-30-2002

Budget for Year : 3
Revised: Apr-29-2002

EXPENDITURES

Item	Approved Budget Amount	Period 1 08/01-01/02	Period 2 02/02-04/02	Period 3	Period 4	Period 5	Period 6	Total	Variance	ct
CONSULTANT/CONTRACTUAL	20,250									
Cons/Contrct Subtotal	20,250									
Grand Total	176,665									

THE
ROBERT WOOD
JOHNSON
FOUNDATION

1/3
EOL

July 17, 2002

CENTRAL FILES
PERMANENT COPY

David E. Joranson, M.S.S.W.
Director
Pain and Policy Studies Group
University of Wisconsin-Madison
406 Science Drive, Suite 202
Madison, WI 53711-1068

Reference: I.D. #036509 - Request for Final Financial Report

Dear Mr. Joranson:

This is in reference to your Robert Wood Johnson Foundation grant in support of the Targeted End-of-Life Projects Initiative: a project to assess states' pain policies.

We have received your final narrative report and have forwarded a copy of this report to Rosemary Gibson for her review. If she has any questions or comments, she will contact you directly.

We look forward to receiving your final financial report by July 30, 2002. If I can assist you further, please contact me at 609-627-5844.

Sincerely,

Sophia Kounelias
Financial Analyst

/SXR

cc: Robert C. Andresen
Rosemary Gibson

PAIN & POLICY STUDIES GROUP

WHO Collaborating Center
for Policy and Communications
in Cancer Care

July 12, 2002

Sophia Kounelias
Financial Analyst
Robert Wood Johnson Foundation
Route 1 and College Road East
Princeton, NJ 08543-2316

Reference: RWJ Grant # 036509
UW 133-CW36

Dear Ms. Kounelias,

Enclosed please find three copies of the Final Grant Report, three copies of the Bibliography, and two copies of the Communications Products for the above referenced grant.

Sincerely,

Janet Kline

Janet Kline, MLS
Program Administrator

Enclosures

UW Comprehensive Cancer Center - University of Wisconsin-Madison Medical School
406 Science Drive, Suite 202 Madison, WI 53711-1068 USA (608) 263-7662 FAX: (608) 263-0259
www.medsch.wisc.edu/painpolicy

FINAL GRANT REPORT

"BUILDING CAPACITY TO PROMOTE PAIN POLICY THROUGH EVALUATION, RESEARCH AND COMMUNICATION"

TARGETED END-OF-LIFE INITIATIVES

GRANT # 036509
AUGUST 1, 1999 -DECEMBER 31, 2001
(EXTENDED TO APRIL 30, 2002)

SUBMITTED
JULY 12, 2002

PAIN & POLICY STUDIES GROUP
406 SCIENCE DR., SUITE 202
MADISON WI 53711-1068
608.263.7662
PPSG@MED.WISC.EDU

1. WHAT WERE THE PROJECT'S OBJECTIVES AND TO WHAT EXTENT HAS THE PROJECT MET THESE OBJECTIVES?

A review of the project's time-line demonstrates that all objectives proposed during the grant have been met in a timely fashion.

Part 1: Policy Evaluation

(1) Guide to Evaluation of Federal and State Policies. We completed the document "Achieving Balance in Federal and State Pain Policy: A Guide to Evaluation" in July 2000, which presents the results of the first systematic evaluation of pain-related policies from the federal government and the 50 states. All policies that were in force and available through March 2000 were examined using a set of well-documented criteria based on a Central Principle that should underlie all pain policy. The document is designed as a workbook to assist professionals and groups who want to learn how to evaluate policies that can affect pain management in their state or at the federal level.

The document has been prepared in a hard-copy format and was disseminated to all Robert Wood Johnson Foundation (RWJF)-supported Community-State Partnerships, other grantees including Last Acts, and to State Cancer Pain Initiatives, State Medical Societies and many other organizations. The document also was prepared in an electronic format and placed on the PPSG website. We automated the policy matrix so that clicking the dot in a cell, which represents an identified policy, links the user directly to a down-loadable electronic document with the full text of the policy, citation, the relevant criteria, a comment, and a link to a more complete discussion of the criteria. The document was made available on CD-ROM for organizations or individuals who made this request. Detail about our dissemination of the Evaluation Guide is available in Question 5.

(2) Changes in Federal and State Policy: 1998-2001. After a careful review of this project we decided that, rather than creating a separate document, this information should be included in the "Annual Review of New State Pain Policies, 2001," which is discussed below.

(3) Annual Reviews of New State Pain Policies. We prepared an "Annual Review of New State Pain Policies, 2000" (Annual Review 2000) and an "Annual Review of New State Pain Policies, 2001" (Annual Review 2001), summarizing all new or amended pain policies from 2000 and 2001, such as the adoption of new intractable pain treatment acts and medical board regulations and guidelines on prescribing controlled substances for pain. Both Annual Reviews contained (a) the cumulative trend of pain policies since 1980, and (b) a state-by-state listing, citation, summary, and commentary for each new policy in the previous year.

Although we proposed to complete each Annual Review by the end of August of that year, we modified this objective so that the reports would be completed by the end of December to be able to evaluate and report on all policies adopted during the calendar

year. As a result, the Annual Reviews represented a full year, rather than a partial year of policy development. Once completed, the Annual Reviews were made available on our website at www.medsch.wisc.edu/painpolicy/publicat/01ppsgar/contents.htm, and were distributed to key individuals and organizations such as health-care providers, patient advocacy groups, state cancer pain initiatives, state government pain commissions, state pain summit meetings and task forces, state legislatures, and medical boards. More detail about our dissemination activities for the Annual Reviews is available in Question 5.

(4) Electronic Access to State Pain Policies. We collected state pain policies by using our electronic legal database (Lexis, from "Lexis-Nexis Research Software") and by periodic direct contact with state agencies, and continually updated the full text database of state pain policies located on the down-loadable PPSG website. The policy database includes all relevant federal and state laws, regulations, and guidelines. The accuracy and completeness of this policy database is assured through an internal quality-control procedure and regular monitoring of the policy environment.

(5) Evaluations of Medical Board Pain Guidelines. We compared (1) state medical board policies adopted before and after the Federation of State Medical Board's "Model Guidelines for the Use of Controlled Substances for the Treatment of Pain" (Model Guidelines), and (2) the Model Guidelines to all policies adopted subsequent to its development. The criteria used in "Achieving Balance in Federal and State Pain Policy: A Guide to Evaluation" guided the evaluation for this project. Policy language that met each criterion was entered into an electronic database. We have analyzed the extent that, when compared to "older" policies, "newer" policies contain language that is balanced, recognizing issues such as the medical use of controlled substances, addressing physicians' concerns about investigation, and accurate in the use of terminology. Although not mentioned in the grant, we are preparing an article describing the results of the content evaluation for publication in a peer-reviewed journal.

Part 2: Empirical Research

(1) Trends in abuse and medical utilization of opioids. PPSG staff annually updated its database regarding the abuse and medical use of opioid analgesics. Abuse data are collected from the Drug Abuse Warning Network (DAWN) of the Substance Abuse and Mental Health Services Administration (SAMHSA); medical use data come from the Automation of Reports and Consolidated Orders System (ARCOS) of the Drug Enforcement Administration (DEA). Our previous research with these data demonstrated that the abuse of opioid analgesics was low and stable over time despite a substantial increase in their medical use. This article was published in 2000 in the *Journal of the American Medical Association*. Efforts are being made to monitor these data to evaluate recent increases that have been reported in the media and by the DEA. Although not mentioned in the grant, we are preparing an article describing the results of an analysis of the abuse and medical use for opioid analgesics between 1994 and 2000 for publication in a peer-reviewed journal.

Part 3: Communications

A major purpose of this grant is to increase awareness of pain policy issues and to support the efforts of individuals and organizations in government and health care to evaluate and improve policies that affect pain management. We proposed to accomplish this goal through several means, including proactive communication of the products from this grant to a broad range of individuals and groups, using means in addition to the ordinary channels of publishing articles in journals. We proposed to: (1) maintain the PPSG website as a source of pain policy information for the public, (2) expand the PPSG list-serve, and (3) provide rapid and efficient technical assistance and dissemination of information. PPSG established a Communications Team to guide efforts to accomplish this objective. More detail is available in our response to Question 5; a summary of the accomplishments follows.

(1) Website: The Team implemented a number of improvements to the website, including an enhanced home-page and site guide, addition of the full text of many new state pain policies, and addition of new links to the site (see Bibliography). Utilization of the site has continued to increase, with approximately 5,800 users per month and a total of about 28,000 hits on our website over a five-month evaluation period.

(2) List-serve: We reviewed this objective and decided that a single list-serve had limited potential for communicating to the broad audience that is interested in pain policy. We decided that it would be preferable for our staff to monitor and participate actively in the growing number of list-serves on topics that relate to pain policy, rather than manage a list-serve aimed at a more limited subscriber audience. We now participate in list-serves of other groups that are interested in oncology and pain, substance abuse, prescription monitoring, pain, and end-of-life issues. Typically, we notify these list-serves of our website, respond to questions and note the availability of particular resources that we have developed. We also post our own questions on a variety of list-serves to stimulate discussion and obtain feedback on policy issues. In addition, we assembled a list of approximately 350 e-mail addresses of key individuals and organizations whom we notify of new products from the PPSG. We believe that this approach has resulted in bringing a greater awareness of our work to a much broader audience of professionals.

(3) Technical assistance and dissemination of information: PPSG has provided a high level of technical assistance to a variety of groups that influence various aspects of pain policy, medical practice and patient care, including the American Cancer Society, the American Bar Association Commission on Legal Problems of the Elderly, the National Association of Attorneys General, the RWJF Community-State Partnerships, the Midwest Bioethics Center, the American Academy of Neurology, a joint committee of three national associations, the American Pain Society, the American Society of Addiction Medicine, and the American Academy of Pain Medicine, and to several state cancer pain initiatives. A more detailed description of these key technical assistance activities is as follows:

(a) The PPSG assisted the American Bar Association Commission on Legal Problems of the Elderly in its preparation of a position statement on a Proposed ABA Policy on Legal Obstacles to Effective Pain Management.

(b) PPSG was invited by the RWJF Community-State Partnership in Kansas to provide a day of technical assistance on issues and opportunities in regulatory policy in the state. PPSG used this opportunity to prepare a protocol for providing technical assistance in the states.

(c) The PPSG was asked to provide comments on a proposed position statement about pain management and public policy to the American Academy of Neurology.

(d) The PPSG was asked to provide extensive policy assistance to a joint committee to achieve consensus on terms related to pain and addiction; the committee was established by three national associations: the American Pain Society, the American Society of Addiction Medicine, and the American Academy of Pain Medicine.

(e) The PPSG was asked to provide technical assistance about state prescription monitoring programs to representatives of the Michigan Hawaii, and Texas Cancer Pain Initiatives. We compiled and sent an extensive list of the resources available.

Information and assistance has also been provided to a variety of government and non-government organizations about how to achieve balanced pain policy, including guidance about how to respond to pain medication abuse and diversion. Such individuals and organizations include the state of Florida Division of Pharmacy Services and the University of Florida, the New Mexico Attorney General, the DEA, and a joint committee of three national associations – the American Pain Society, the American Society of Addiction Medicine, and the American Academy of Pain Medicine. A more detailed description of key technical assistance activities is as follows:

(a) Representatives of the U.S. Drug Enforcement Administration contacted the PPSG in March, 2001, to explore the development of a pain forum about the need for a balanced response to the extensive media attention surrounding OxyContin® abuse and diversion in order to avoid responses that would interfere in relief of pain, but would also address the healthcare system's responsibility to avoid contributing to the problem. Subsequently, the PPSG collaborated with Last Acts and the American Pain Society, in conjunction with Burness Communications, to organize several meetings of an ad hoc Pain Forum to explore the issues and to develop a joint consensus statement. The consensus statement, which was endorsed by the DEA and 21 health-care and pain organizations, including

the American Cancer Society and the American Medical Association, was released at a national press briefing on October 23, 2001. Since then, a total of 42 organizations have endorsed the consensus statement.

(b) Following technical assistance provided to the Michigan Cancer Pain Initiative and the Michigan Commission on End-of-Life Care, Wayne State University sponsored a conference to report the results of the Commission, which made extensive use of resources and guidance from PPSG. David Joranson was invited to present an analysis of the recommendations from the report and how these would improve Michigan policy on end-of-life care compared with the rest of the country.

(c) The PPSG was invited by the American Cancer Society (ACS) to participate in their meeting of the Cancer Pain Management Policy Review Group. The purpose of this meeting was to assist in developing an ACS policy statement in response to the abuse and diversion of pain medications and to ensure that medical practice and patient care are not compromised. The PPSG provided subsequent technical assistance in the drafting of the ACS policy.

(d) Last Acts invited David Joranson to serve as a member of the Provider Education Committee, as well as the Policy Committee, which are standing committees of Last Acts.

As interests in pain management and end-of-life care expand, coupled with the substantial media attention surrounding OxyContin® abuse and diversion, requests for our assistance and for providing information sometimes exceed our capacity to respond (and still accomplish our other work under the grant). The recent policy environment relating to pain management and opioid analgesics is becoming increasingly negative and challenging. We developed a data collection form, as well as a procedure to use it in order to assure we capture the full extent of our technical assistance efforts.

Within the project period, the PPSG Communications Team continued to utilize a strategy for publicizing articles to be published in major journals, as well as other PPSG documents. We used the dissemination of our April 5, 2000 article in the *Journal of the American Medical Association* as the model. The strategy consists of two components: (1) to ensure that the article and the electronic notification communicated the message of the article, and (2) to disseminate this message to our main audiences, including health-care professional groups, government, and the public. This dissemination strategy precipitated numerous compliments regarding our products and publications.

2. WHAT INTERNAL SHORTFALLS, LIMITATIONS, OR CHALLENGES DID THE PROJECT ENCOUNTER THAT WERE RELATED TO ITS FUNDING LEVEL, DESIGN, COLLABORATIONS, STAFFING, OPERATIONS, OR OTHER PROJECT FACTORS? DID ANY CHALLENGES INTERNAL TO THE NATIONAL PROGRAM AFFECT THE PROJECT?

We encountered an ongoing challenge in developing our communications program. A Communications Specialist position was created at the beginning of this project and an individual was hired into the position. The person that we hired was not a good fit and left after four months. We re-evaluated our needs and the skills necessary for the position. We hired Ms. Renie Shapiro, a senior communications consultant, to assist us in developing a communications strategy and advise us with working with the media. A Policy Specialist with the PPSG became our Communications Coordinator. We believed it would be useful to have a person knowledgeable in pain policy responsible for helping our Director communicate our messages. However, she moved out of state a year-and-a-half later and we once again needed to fill this position. Our current Communications Specialist, Ms. Jody Jorenby, has been employed in this capacity for eight months and has provided valuable assistance in our policy program, as well as communicating our work and messages to a range of audiences. We are satisfied that we have addressed this challenge effectively.

During the second year of the project, with relatively short notices, the UW Medical School asked the PPSG to move to another location. This move necessitated two weeks of down time to prepare for the move, make the move, and accomplish a complete computer network reconfiguration at the new location. We transitioned our computer technical support from a staff member to a contract for computer support services from a UW group, based on a cost-benefit analysis necessitating release of the staff member who had provided computer and technical support. This challenge is behind us and we are very satisfied with our new location and computer support.

3. WHAT PROBLEMS OR SUCCESSES WERE CAUSED BY FACTORS EXTERNAL TO THE PROJECT?

During the project period, policy issues have become an increasingly recognized part of the national and state discussion about pain, and have been gaining attention as an important component of public health. Efforts of Last Acts and state Cancer Pain Initiatives, as well as the OxyContin® problem, have resulted in increased demand for our work.

Greater recognition of the importance of pain management and public policy has occurred during a time of vast media, professional, and governmental attention to the abuse and diversion of OxyContin®. We experienced an increase in the requests for technical assistance from health-care professionals, regulators, policy makers, and members of the media. In order to more directly address the need for a balanced response, the PPSG engaged directly with the U.S. Drug Enforcement Administration (DEA) to hold a series of meetings to bring together members of national health-care and

regulatory organizations. The purpose of the meetings was to develop a joint consensus statement emphasizing the need for a balanced approach to diversion and abuse of opioid pain medications so that efforts to address diversion do not interfere with medical practice and patient care. The joint consensus statement was developed and endorsed by the DEA and 42 professional health-care and pain-related organizations. In addition, PPSG staff members were frequently requested to make presentations about issues relating to the abuse, diversion, and medical availability of opioid analgesics when treating pain. We received many requests for updating and publishing information related to the recent medical use and abuse of Schedule II opioid analgesics, which is now being prepared for publication. This increased demand has strained the resources of our staff, but has given us the opportunity to mediate the potential negative effects of this issue.

The OxyContin® controversy has also resulted in an increase in the interest in and utilization of our products. For example, the frequency of PPSG website hits has continued to increase throughout the last year, and demand for the Evaluation Guide led to a second printing of 100 copies. Given these developments at the federal and state levels, it is likely that there will be continued increases in requests for information and technical assistance, particularly since organizations are sponsoring more and more state-level initiatives. The numerous state-level activities promoting improvements in pain management and end-of-life care has necessitated reallocation of grant resources so that we can continue to respond to opportunities and requests. It is clear that our work is in demand by these groups and, although much of our work is available on the website, this is not always sufficient to provide expert guidance during dynamic policy activity.

4. IF YOU WORKED IN COLLABORATION WITH OTHER ORGANIZATIONS, OR DEPENDED ON OTHER ORGANIZATIONS OR INSTITUTIONS TO MEET THE OBJECTIVES OF THIS PROJECT, HOW DID THOSE COLLABORATIONS WORK?

The PPSG relies on data from two government organizations to support our studies of medical use and abuse of opioid analgesics: the Drug Enforcement Administration (DEA) and the Substance Abuse and Mental Health Services Administration (SAMHSA).

We request the medical use data for individual opioid analgesics directly from the DEA Targeting and Analysis Unit of the Office of Diversion Control, which has been extremely responsive to our various requests. The Unit continues to provide us with both hardcopy and disk-copy of the Automation of Reports and Consolidated Orders System (ARCOS) data on which our analysis of consumption is based. We do not have to file Freedom of Information Act requests and are very satisfied with the collaboration.

The data for abuse of opioid analgesics come from the Drug Abuse Warning Network (DAWN), which is an annual report of SAMHSA within the U.S. Department of Health and Human Services. As a result of feedback from DAWN users, including the PPSG, staff members at SAMHSA have re-designed the DAWN report to make it more user-friendly and pharmacologically correct. As a result, the current PPSG in-house database has been slightly revised and updated to reflect the changes. Following this,

routine data collection and maintenance will be continued. Our collaboration with SAMHSA is excellent.

Finally, our collaboration with the American Alliance of Cancer Pain Initiatives (AACPI) continues to be positive and serves as an effective communications channel for our products to the AACPI audience throughout the states. The AACPI also informs us of issues related to policy development or other regulatory activity at the state level.

We have been pleased with our collaborations with Last Acts, and Midwest Bioethics and their Community-State Partnerships on End-of-Life Care.

5. WITH A PERSPECTIVE ON THE ENTIRE PROJECT, WHAT HAVE BEEN ITS KEY COMMUNICATIONS ACTIVITIES?

PPSG Website

The PPSG website has been in service since July 1997. In the past five months,[1] the website has averaged 59,929 hits, with a monthly average of 12,674 users from around the world. There has been over a 280% increase in the number of monthly hits over the course of this project.[2]

Until June 2001, the website was maintained by the PPSG's Information Technology Manager. Beginning July 2001, responsibility for maintaining and expanding the website was assumed by Martha Maurer, Policy Analyst. Maintaining the website involved updating an interactive data-base of policies adopted by state and national boards, legislatures and organizations, adding the new policies as hypertext markup language (HTML) documents, periodically checking website links to insure that they are current and functional, and making any necessary changes to the format of website pages. During this time, PPSG staff met to consider reformatting the "top pages" (see below) of the website. Several modifications were made to increase the format consistency of the pages within the website and to improve the descriptions of our products and instructions to users, all of which will ultimately enhance user navigability. Monthly reports were generated to track the number of website hits and users and to determine the policy documents that are viewed most often by these users. The website e-mail account was also checked weekly for user feedback, which was then either answered by the Policy Analyst that maintains the website or was directed to the appropriate PPSG staff member(s).

During the project period there were 22 new policies adopted to address the use of controlled substances for pain management. State legislatures, state medical boards, state pharmacy boards, state nursing boards, and national organizations developed these policies. Our Policy Analysts collected the policies and converted them to Microsoft Word format either by typing or scanning a hard-copy, or converting an already-extant electronic document from another file format. All policies were then converted to HTML

[1] Average is based on the usage statistics reported for December 2001 through April 2002, the most recent months for this project period.

[2] The project period is July 2000 through April 2002

documents, formatted in the style of other PPSG website documents, and then uploaded to our website.

Several articles and other publications were made available on the PPSG website during the project period. The publication, "Achieving Balance in Federal & State Pain Policy: A Guide to Evaluation," and the article entitled "Pharmacists' Knowledge and Attitudes Towards Opioid Pain Medications in Relation to Federal and State Policy," which was published in the *Journal of the American Pharmaceutical Association*, were made available on the PPSG website in three different formats. The first of these was the full text in Adobe Acrobat PDF format, which users could open and view on their browsers. The second was an interactive PDF version of the document that permits users to view any particular section of the document without having to wait for the entire file to download. The third way was an interactive HTML version of the document that could be viewed using virtually any web browser. This interactive HTML version also permitted the viewer to see any part of the document without having to wait for it to download.

Other articles were made available on the PPSG homepage in an Adobe Acrobat PDF format; these include "Pain Management and Prescription Monitoring," "Pain Management, Controlled Substances, and State Medical Board Policy: A Decade of Change," and "Controlled Substances and Pain Management: Changes in Knowledge and Attitudes of State Medical Regulators."

Index of PPSG website "top pages":

- Home-Page
- Is methadone maintenance the last resort for some chronic pain patients? *American Pain Society Bulletin* 1997;7(5):1,4-5.
- Data-base of Statutes, Regulations, and Other Governmental Policies
- *Model Guidelines for the Use of Controlled Substances for the Treatment of Pain*
- U.S. Pain Policy Resources
- Selected Readings
- Controlled substances, medical practice and the law. In: *Schwartz HI. Psychiatric Practice Under Fire: The Influence of Government, the Media and Special Interests on Somatic Therapies*. Washington, DC: American Psychiatric Press, Inc., 1994:173-194.
- State controlled substances laws and pain control. *American Pain Society Bulletin* 1992;2(3):10-11, 15.
- *Annual Review of State Pain Policies, 2000*
- *Cancer Pain Relief: A Guide to Opioid Availability*

Other Communication Efforts

In addition to the activities relating to the website and technical assistance mentioned under Question 1, the following description provides further information about key activities. Complete information about the communication activities is available in the bibliography.

Pain Forum. The PPSG collaborated with the U.S. Drug Enforcement Administration (DEA) to hold a series of meetings to bring together members of national health-care and regulatory organizations. The purpose of the meetings was to develop a joint consensus statement that emphasizes the need for a balanced approach to diversion and abuse of opioid pain medications so that efforts to address diversion do not interfere with medical practice and patient care. The joint consensus statement was developed and ultimately endorsed by 42 professional health-care and pain-related organizations. Appointment of DEA Chief Asa Hutchinson, as well as national events, delayed the press briefing until October 2001.

Publicity of the DEA Joint Consensus Statement. After its release at a national press briefing in October 2001, we publicized the DEA consensus statement via our website and an e-mail broadcast to state and national colleagues

Publicity for the Article Published in the *Journal of the American Pharmaceutical Association.* We believe that we were successful in reaching our key audiences. We mailed a copy of the article and press release directly to all state medical and pharmacy boards and state medical societies. In addition, we notified a large number of individuals and organizations via an e-mail broadcast of the availability of the article on our website. The article and its press release are on our website and are frequently accessed by users; there were (and continue to be) numerous placements in media aimed at the public.

Publicity for Two Articles Published in the *Journal of Pain and Symptom Management*. A hard copy of "Pain Management, Controlled Substances, and State Medical Board Policy: A Decade of Change" (accompanied by a hard copy of the *Annual Review of State Pain Policies for 2001,* an informational letter, and the PPSG brochure) was sent to Senators and U.S. House of Representative members. An Adobe Acrobat PDF version of the document was posted to our website and an e-mail broadcast was sent out to a multitude of individuals and organizations, including several listserves, notifying them of the availability of the article on our website. The publication was announced in BoardNet News, a publication of the Federation of State Medical Boards.

Dissemination of "Pain Management and Prescription Monitoring" to key audiences was also a successful endeavor: An e-mail broadcast was sent to numerous individuals, organizations, and listserves to notify about the article's availability on our website. Hard copies of the article were distributed upon the request of interested individuals.

PPSG Brochure. This brochure has been included in all mailings and continues to be distributed at state, national, and international conferences.

Publicity for the "*Annual Review of State Pain Policies, 2000.*" Key audiences were successfully targeted in the dissemination of this report. We mailed a printed copy of the document directly to all state legislative librarians, state medical societies, state medical boards, the state cancer pain initiatives in the states with policy changes as well as other key individuals. We also notified a large number of individuals and organizations via an e-mail broadcast of the availability of the document on our website. Recipients of this

e-mail notification include the Liaison Committee on Pain and Addiction, the Community-State Partnerships on End-of-Life Care, the National Association of Drug Diversion Investigators Prescription Drug Abuse listserve, the OncoPain listserve, the Last Acts Discussion listserve, the State Cancer Pain Initiatives listserve, the Project on Pain Management and Chemical Dependency listserve, and to other professionals interested in pain management policy. This document was also listed in the Last Acts Policy Newsletter, *Innovations in End-of-Life Care.*

Publicity for the "*Annual Review of State Pain Policies, 2001.*" An e-mail broadcast, coinciding with the announcement of the publication of "Pain Management, Controlled Substances, and State Medical Board Policy: A Decade of Change," was sent to individuals and organizations, including several listserves, notifying them of the article's availability on our website. A hard copy of each document was also sent to Senators and U.S. House of Representative members, along with an informational letter and a copy of the PPSG brochure. A link to the URL containing the document on the PPSG website is available on the National Association of State Controlled Substances Authorities website.

Participation in AMA Media Briefing. PPSG Assistant Director, Aaron Gilson, presented findings and messages from the "Annual Review of State Pain Policies, 2001" at an American Medical Association's media briefing about pain management issues. A link to the AMA website's notification of the briefing was placed on the PPSG website.

Participation in an Audio Program. PPSG Director, David Joranson, participated in Part I of an audio program for State Initiatives in End-of-Life Care's four-part audio series, *Heart-to-Heart: Improving Care for the Dying through Public Policy.* The tapes are 30- to 40-minutes of narration and in-depth commentary by leading state and national experts offering tips about how to make policy change. Community-State Partnerships to Improve End-of-Life Care coordinated publicity and sales of the audio series.

Continued Dissemination of "*Achieving Balance in Federal & State Pain Policy: A Guide to Evaluation.*" Due to high demand for this document, 300 reprints were made in November 2000. There was a second e-mail notification of its availability to academic leaders, pain management advocates, newsletters, professional societies and listserves. In July of 2001, 100 additional reprints were made. A letter and a copy of the publication were sent to pharmacy law professors for review and comments. Hard-copies were also sent to several colleagues and organizations. Hard-copies of this document continue to be requested through the PPSG website.

Presentations at National Conferences. PPSG provided presentations on trends and issues in pain policy to participants at a number of conferences sponsored by national organizations. Among these were the Pain Management and Chemical Dependency conference, National Association of Boards of Pharmacy annual meeting, American Alliance of Cancer Pain Initiatives national meeting, National Association of State Controlled Substances Authorities, and American Society of Law Medicine & Ethics meeting. A complete list is included in the bibliography.

David Joranson also provided a presentation entitled "Relieve Pain, Prevent Diversion" for the American Cancer Society's Pain Management Policy Review. He discussed such topics as the abuse and diversion of pain medications, the media coverage of OxyContin®, the problems with the domestic and international opioid distribution systems, and the approaches to stopping diversion.

6. WHAT WERE THE PROJECT'S OTHER SOURCES OF SUPPORT?

This project had no other sources of support. The other activities of the group were international projects related to our status as the World Health Organization Collaborating Center for Policy and Communications in Cancer Care.

Office space for the Pain & Policy Studies Group (PPSG) and this project was provided by the Medical School of the University of Wisconsin-Madison.

7. WHAT WAS THE SIGNIFICANCE OF WHAT WAS ACCOMPLISHED BY THE PROJECT?

This project was significant because it established pain policy as part of pain management, end-of-life care, medical regulation, and controlled substances regulation. The project accomplished this by introducing into the literature the principle of "balance" with respect to the imperative that efforts to address abuse of drugs should not interfere with medical use and patient care; it established the first set of policy research criteria in the field of controlled substances, medical and pharmacy policy related to pain; it produced the first systematic evaluation of federal and state policies; the evaluation has been used to guide policy reform in several states; it provided professionals, policy makers, regulators, and the public with internet access to policies of the federal government and the states that are relevant to the treatment of pain; it helped to improve the knowledge of medical regulators, and to evaluate and develop new, more balanced, state medical board pain policies; it actively published and disseminated this new knowledge and the outcomes of its research to a broad audience of policy makers, professionals, and the public in the U.S. The project also led to a better understanding of the medical use and abuse of pain medications, and to improvement of an important federal drug abuse information system.

8. WHAT LEASONS DID YOU, AS PROJECT DIRECTOR OF A PROJECT IN A NATIONAL PROGRAM, LEARN FROM UNDERTAKING THIS PROJECT?

It was an important learning experience for us to be involved in the national program aimed to improve end-of-life care. Although we are a small part of the national program, I think we had an important influence, but we could have collaborated with program partners even more than we did. In addition, we probably underestimated the

demand for our work and could have had an even greater influence had we strategized earlier on and prepared.

We are aware of a number of positive outcomes in the policy arena that were related to our work. We have proposed studying these effects, but it would have been more efficient to include such studies during the course of the project.

There is a long way to go to improve end-of-life care in the U.S., and we are hopeful that the initial progress of the National Program can be sustained and enhanced because it is likely that the early successes were in the easiest places.

9. WHAT ARE THE POST-GRANT PLANS FOR THE PROJECT IF IT DOES NOT CONCLUDE WITH THE GRANT?

All of the projects proposed in this grant were finite in nature. Additional funds have been awarded from the Robert Wood Johnson Foundation to update and quantify the Evaluation Guide and to create a Report Card of state policies. Since funding was not approved for the full proposal, additional funding is being sought.

Assuming funds are available, the PPSG will continue its mission to identify and evaluate federal and state pain policy. The results will be published and added to our website, which will be maintained, enhanced and updated. We also plan to continue to publish reports on trends in medical use and abuse of opioids, the first of which was supplied by this grant.

10. HOW DO YOU ASSESS THE FOUNDATION'S ROLE AND THE NPO'S ROLE?

The Foundation has provided extremely important support for us to develop pain policy into an increasingly recognized part of medical practice, patient care, federal and state policy, and abuse and diversion of opioids. We have found the Foundation's policies to be reasonable. Foundation staff has been very responsive to us, and have provided valuable guidance.

FINAL PROGRESS REPORT

BIBLIOGRAPHY

"BUILDING CAPACITY TO PROMOTE PAIN POLICY THROUGH EVALUATION, RESEARCH AND COMMUNICATION"

TARGETED END-OF-LIFE INITIATIVES

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PAIN & POLICY STUDIES GROUP
406 SCIENCE DR., SUITE 202
MADISON WI 53711-1068
608.263.7662
PPSG@MED.WISC.EDU

BIBLIOGRAPHY

Books and Reports

Joranson DE, Gilson AM, Ryan KM, Maurer MA, Nischik JA, Nelson JM. *Achieving Balance in Federal and State Pain Policy: A Guide to Evaluation.* Madison, Wisconsin: Pain and Policy Studies Group, University of Wisconsin Comprehensive Cancer Center, 2000. Also available on our website www.medsch.wisc.edu/painpolicy

Joranson DE, Maurer MA, Gilson AM, Ryan KM, Nischik JA. *Annual Review of State Pain Policies, 2000.* Madison Wisconsin: Pain & Policy Studies Group, University of Wisconsin Comprehensive Cancer Center; 2001. 500 copies printed and 250 disseminated to date. Also available on our website at www.medsch.wisc.edu/painpolicy

* Joranson DE, Maurer MA, Gilson AM, Ryan KM. *Annual Review of State Pain Policies, 2001.* Madison Wisconsin: Pain & Policy Studies Group, University of Wisconsin Comprehensive Cancer Center; 2002. 500 copies printed and 250 disseminated to date. Also available on our website at www.medsch.wisc.edu/painpolicy

Articles

* Dahl JL, Bennett ME, Bromley MD, and Joranson DE. "Success of the State Pain Initiatives." *Cancer Practice.* 10(May/June): S9-S13, 2002.

Dahl JL, Joranson DE, and Stein W. "Pain Management Standards: Their Role in Improving the Quality of Care." *Annals of Long-Term Care.* 9(August): 25-26, 2001.

* Dubois MY, Livovich J, Fleetwood J, Joranson DE, and Vaillancourt PD. "Ethics Forum - Incompetence, Drug Diversion or Pain Management: Trying to Draw the Line." *Pain Medicine.* 3(1): 73-77, 2002.

Gilson AM, and Joranson DE. "Controlled Substances and Pain Management: Changes in Knowledge and Attitudes of State Medical Regulators." *Journal of Pain and Symptom Management.* 21(March): 227-37, 2001.
Also available on our website at www.medsch.wisc.edu/painpolicy

Gilson AM, Joranson DE, and Ryan KM. "Medical Use and Abuse of Opioids" (editorial). *Journal of Pharmaceutical Care in Pain & Symptom Control.* 8(4): 1-4, 2000.
Also available on our website at www.medsch.wisc.edu/painpolicy

Joranson DE. "Improving Pain Policy in the United States and the World" *Update – Pharmaceutical Distribution and Marketing Audits, Inc.* 8(2): 6, 9, 2001.

Joranson DE, and Berger JW. "Regulatory Issues in Pain Management." *Journal of the American Pharmaceutical Association.* 40 (September/October): S60-S61, 2000.

* Joranson DE, Carrow GM, Ryan KM, et al. "Pain Management and Prescription Monitoring." *Journal of Pain and Symptom Management.* 23(March): 231-238, 2002.
Also available on our website at www.medsch.wisc.edu/painpolicy

Joranson DE, and Gilson, AM. "Pharmacists' Knowledge and Attitudes About Opioid Pain Medications in Relation to Federal and State Policy." *Journal of the American Pharmaceutical Association.* 41(March/April): 213-220, 2001.
Also available on our website at www.medsch.wisc.edu/painpolicy

Joranson DE, and Gilson, AM. "Pharmacists' Knowledge and Attitudes About Opioid Pain Medications in Relation to Federal and State Policy." *Journal of the Pharmacy Society of Wisconsin* (May/June): 4-10, 2001. (published previously in Journal of the American Pharmaceutical Association. 41(March/April): 213-220, 2001)

* Joranson DE, Gilson AM, Dahl JL, and Haddox JD. "Pain Management, Controlled Substances, and State Medical Board Policy: A Decade of Change." *Journal of Pain and Symptom Management.* 23(February): 138-147, 2002. Also available on our website at www.medsch.wisc.edu/painpolicy

Joranson DE, and Nischik JA. "The Pain & Policy Studies Group: Past, Present, and Future" *Forum- North Carolina Medical Board.* (2): 9, 2001.

Joranson DJ, Ryan KM, Gilson AM, and Dahl JL. "Trends in Medical Use and Abuse of Opioid Analgesics." *Journal of the American Medical Association.* 282(April): 1710-1714, 2000.
Also available on our website at www.medsch.wisc.edu/painpolicy

Joranson DJ, Ryan KM, Gilson AM, and Dahl JL. "Letter to the Editor: In Reply to 'Reporting Drug Abuse in the Emergency Department.'" *Journal of the American Medical Association.* 284 (June): 564, 2000.

Brochures and Fact Sheets

"Definitions Related to the Use of Opioids for the Treatment of Pain"; A consensus document from the American Academy of Pain Medicine, the American Pain Society, and the American Society of Addiction Medicine, 2001.

"Promoting Pain Relief and Preventing Abuse of Pain Medication: A Critical Balancing Act"; A joint statement from 21 Health Organization and the Drug Enforcement Administration, 2001.

"Pain & Policy Studies Group: Promoting Pain Relief Through Balanced Public Policy and Communications." The Pain & Policy Studies Group, 2001.

Sponsored Workshop

"Pain, Controlled Substances and Pharmacy in Wisconsin," February 23, 2001, UW Hospital and Clinics. Attended by 6 professors, pharmacists, and leaders of the Pharmacy Society of Wisconsin.

Presentations and Testimony

Aaron M. Gilson, "Pain Management and Drug Abuse: Incidence, Effects on Practice, and Possible Solutions" at various healthcare organizations in Milwaukee, WI between August 2000 and September 2001.

David E. Joranson, "Trends and Issues in Pain-Related Policies: Laws and State Medical Board Guidelines," at Contemporary Concepts in Cancer Pain: Tenth Annual Conference of the Pennsylvania Cancer Pain Initiative, Pennsylvania Cancer Pain Initiative, September 23, 1999.

David E. Joranson, "Testimony of David E. Joranson," to the U.S. Senate Hearing on Pain Management and Improving End of Life Care, October 13, 1999, Washington D.C., Requested by Senator Edward Kennedy, October 1, 1999.

David E. Joranson, "Trends and Issues in State Pain Policy," at Health Care and Law in the New Millennium: Patients' Rights at the Forefront, the American Association of Nurse Attorneys, October 22, 1999, Denver, Colorado.

David E. Joranson, "Evaluation of State Pain Policy: Is It Balanced?" at Pain Management: Medical, Legal and Ethical Issues, Baystate Health System Office of Continuing Education, November 10, 1999, Holyoke, Massachusetts.

David E. Joranson, "Guidelines, Trends and Issues in the State Pain-Related Policy," at the 21st Annual Cancer Symposium: Palliative Issues and Supportive Care in the Cancer Patient, Northwest Community Hospital, November 13, 1999, Arlington Heights, Illinois.

David E. Joranson, "Improving Pain Management Strategies," at Technical Consultation for the Life Project, Kansas Community State Partnership, December 14, 1999, Kansas City, Kansas.

David E. Joranson, "Overview of Regulatory History," at Chronic Pain: Medical Management and Regulatory Issues, North Broward Hospital District, April 8, 2000, Pompano Beach, Florida.

David E. Joranson, "Controlled Substances: Opioids for Chronic Pain and the Anxious

Physician," at the Pain Management Seminar, Purdue Pharma L.P., April 18, 2000, Des Moines, Iowa.

David E. Joranson, "Progress and Issues in Pain Policy," at Continuing Education in Pain Management, VA Hospital, May 4, 2000, Northport, New York.

David E. Joranson, "Developments in National and State Policies Affecting Pain Management: National Update on Policies and Legislation," at the 11th National Meeting for State Cancer Pain Initiatives, American Alliance of State Cancer Pain Initiatives, June 16, 2000, Kansas City, Missouri.

David E. Joranson, "Is It Safe to Prescribe Opioids?," at Pain Management for the Primary Care Clinician, American Pain Society, September 15, 2000, Chicago, Illinois.

Karen M. Ryan, "Use and Abuse of Opioid Analgesics in the United States," at the Janssen-Cilag Sponsored Symposium of the Third Congress of the European Federation of IASP Chapters, September 28, 2000, Nice, France.

David E. Joranson, "Regulatory Barriers to Pain Management and National Cancer Center Control Policy," at Roundtable Discussion on Quality of Life for Cancer Survivors, National Cancer Legislation Advisory Committee, October 2 – 3, 2000, Washington, DC.

David E. Joranson, "A Report Card on State Initiatives Involving Pain Management," at the 16th Annual Educational Conference, The National Association of State Controlled Substances Authorities, October 31 – November 4, 2000, Louisville, Kentucky.

David E. Joranson, served as moderator for Tri-State Pain Summit on Regulatory Issues, Shenandoah Pain Project & *Pain Relief*/USA, Inc., November 6, 2000, Winchester, Virginia.

David E. Joranson, "Pain Management: Risk Assessment and Legal Concerns," at End of Life Decision Making: What Have We Learned Since Cruzan?, American Society of Law, Medicine & Ethics, November 17 – 18, 2000, Kansas City, Missouri.

David E. Joranson, "Practical Issues for Regulators," at the Fourth Conference on Pain Management and Chemical Dependency, December 7 – 9, 2000, Washington, DC.

David E. Joranson, "Opioid Therapy: Medico/Legal Issues," at American Academy of Pain Medicine's 17th Annual Meeting with Comprehensive Review Course, February 15 – 18, 2001, Miami, Florida.

David E. Joranson, "Analgesic Regulatory Affairs," at the 20th Annual Scientific Meeting, American Pain Society, April 19 – 22, 2001, Phoenix, Arizona.

David E. Joranson, served as moderator at Pain Forum Meeting with Drug Enforcement

Administration, April 23 - 24, 2001, Chicago, Illinois.

David E. Joranson, "The Last Link in the Chain: Results of a survey of Wisconsin Pharmacists," at Pharmacy Society of Wisconsin Educational Conference, April 27, 2001, Madison, Wisconsin.

David E. Joranson, "Opioids and the Law," at National Association of Boards of Pharmacy 97th Annual Meeting, May 5 - 9, 2001, Seattle, Washington.

David E. Joranson, "Pain Management Standards: Their Role in Improving the Quality of Care," at American Geriatric Society, May 12, 2001, Chicago, Illinois.

David E. Joranson, "Building a Regulatory Agenda in the CPI Movement," at the 12th National Meeting for State Cancer Pain Initiatives, American Alliance of Cancer Pain Initiatives, June 14-16, 2001, Madison, Wisconsin.

David E. Joranson, "Stopping Abuse of Pain Medications: A Critical Balancing Act," at Pain Forum II, Drug Enforcement Agency, July 11, 2001, Chicago, Illinois.

David E. Joranson, "Relieve Pain, Prevent Diversion," at American Cancer Society's Cancer Pain Management Policy Review Group, American Cancer Society, July 20, 2001, Washington, DC.

* David E. Joranson, "Legal and Regulatory Issues of Pain Management," at Wayne State University School of Medicine and College of Nursing and Blue Cross Blue Shield of Michigan Department of Health Care Education's Policy and Practice of Pain Management, September 7, 2001, Detroit, Michigan.

* David E. Joranson, "Addressing Regulatory Issues in Pain Management," at the HealthPartners Institute for Medical Education continuing professional development program, October 18, 2001, Minneapolis, Minnesota.

* David E. Joranson, "Regulatory Issues Surrounding the Use of Opioids," at Caremark Prescription Services Presentation, October 30, 2001, Mt. Prospect, Illinois.

* David E. Joranson, "The Legal and Regulatory Aspects of Opioid Prescribing: How WV Stacks Up," at the Pain Management at the End of Life: A Statewide Summit, November 2, 2001, Flatwoods, West Virginia.

* David E. Joranson, "A Balanced Approach to Prescription Drug Diversion Responses," at the National Association of Attorneys General Prescription Drug Abuse Task Force Meeting, November 16, 2001, Washington, DC.

* David E. Joranson, "Opioid Availability in the United States and the World," at a Public Health Seminar, University of Wisconsin, December 3, 2001, Madison, Wisconsin.

* David E. Joranson, "A National Perspective on Pain Policy," at the Florida Partnership for End-of-Life Care's Forum on Pain Policy: Balancing Patient Care and Drug Abuse Prevention, January 14, 2002, Tallahassee, Florida.

* David E. Joranson, "Balancing Drug Abuse Prevention and Pain Relief: The Study of Public Policy," at the University of Florida Health Sciences Center, January 15, 2002, Gainesville, Florida.

* David E. Joranson, "Regulatory Issues in Opioid Prescribing," at the Janssen Pharmaceutica Speakers Training Meeting, February 8, 2002, Orlando, Florida.

* Aaron M. Gilson, "Recent Trends in State Policies Governing Pain Medications: Findings from the 2001 Annual Report," at American Medical Association Media Briefing About Pain Management, February 21, 2002, New York, New York.

* David E. Joranson, "Pain Management and Regulatory Barriers: How Does Pennsylvania Stack Up?," at the 11th Annual Conference of the Pennsylvania Cancer Pain Initiative, April 5, 2002, Harrisburg, Pennsylvania.

* David E. Joranson, "Guidelines and Prescribing Principles for Opioid Therapy," at a continuing education program, April 5, 2002, Hershey, Pennsylvania.

* David E. Joranson, "..." at the Ohio Pain Initiative Pain Summit 2002: Breaking the Barriers to Pain Management, April 27, 2002, Columbus, Ohio.

World Wide Web Sites

www.medsch.wisc.edu/painpolicy
Provides full text of individual state pain policies and pain related federal policies, links to other pain organizations, a glossary of terms and full text of articles published by the PPSG. Madison, WI: Pain & Policy Studies Group. Estimated 5,862 visits per month.

Audio-Visuals and Computer Software

* *Heart-to-Heart: Improving Care for the Dying through Public Policy, Part I: Pain Management*, a 30-40 minute audio tape. State Initiatives in End-of-Life Care, DATE.

Press Kits and News Releases

A news release on the *Journal of the American Medical Association* article "Trends in Medical Use and Abuse of Opioid Analgesics", mailed by JAMA on March 30, 2000 to 1500 reporters

nationally. Also accessible to over 2,000 domestic and international journalists through "EurekAlert!" (a Web site for journalists maintained by the American Association for the Advancement of Science).

A news release on the *Journal of the American Medical Association* article "Trends in Medical Use and Abuse of Opioid Analgesics", mailed by the PPSG on April 1, 2000 to 413 state medical societies, state medical boards, state boards of pharmacy, attorney generals, grant advisors, academic leaders and pain management advocates. One hundred sixty-six academic leaders, pain management advocates, newsletters, professional societies and listserves were notified through email.

An e-mail news release on the *"Annual Review of State Pain Policies 2000"* was broadcasted to 173 academic leaders, pain management advocates, newsletters, professional societies and listserves on March 16, 2001.

An e-mail news release on *"Achieving Balance in Federal and State Pain Policy: A guide to Evaluation"* was broadcasted to 173 academic leaders, pain management advocates, newsletters, professional societies and listserves on March 16, 2001.

An e-mail news release on the *Journal of the American Pharmaceutical Association* article "Pharmacists' Knowledge and Attitudes about Opioid Pain Medications in Relation to Federal and State Policy" article was broadcasted to 173 academic leaders, pain management advocates, newsletters, professional societies and listserves on April 3, 2001.

* An e-mail news release on "*A Joint Statement from 21 Health Organizations and the Drug Enforcement Administration. Promoting Pain Relief and Preventing Abuse of Pain Medications: A Critical Balancing Act*" was disseminated to 330 academic leaders, pain management advocates, newsletters, professional societies and listserves on October 24, 2001.

* An e-mail news release on the "*Annual Review of State Pain Policies, 2001*" and the *Journal of Pain and Symptom Management's* article "Controlled Substances and Pain Management: Changes in Knowledge and Attitudes of State Medical Regulators" was broadcasted to 345 academic leaders, pain management advocates, newsletters, professional societies and listserves on February 28, 2002.

* An e-mail news release on the *Journal of Pain and Symptom Management's* article "Pain management and prescription monitoring" was broadcasted to 345 academic leaders, pain management advocates, newsletters, professional societies and listserves on April 3, 2002.

Print Coverage

"States are Relaxing Rules on Painkillers: Improving Care at the End of Life," in *The States*, May 1999.

"Web Site Offers Pain Management Policy Information," in the *Oregon State Board of Pharmacy Newsletter*, August 1999.

"Can Doctors Put their Fears to Rest?," in *Medical Economics,* February 21, 2000.

"Highlight: The Pain & Policy Studies Group (PPSG)," in *ASPMN Pathways*, March/April 2000.

"More Opiates Used to Treat Severe Pain," in *Reuter's Health Information*, April 4, 2000.

"Abuse of Opioid Painkillers by Patients is Uncommon, Study Finds," in *Oncology Times*, April 5, 2000.

"High Use of Narcotic Painkillers is Not Linked to Aabuse," in *The Oregonian*, April 5, 2000.

"Study Finds Drugs for Pain Not Abused: Results Support Efforts to Manage Pain in People with Long-Term Illnesses," in *The Milwaukee Journal Sentinel*, April 5, 2000.

"Study: Narcotic Abuse May be Overstated," in *Wisconsin Week*, April 5, 2000.

"Less Pain Means Gain for Medical Treatment," in *The Daily Oklahoman*, April 11, 2000.

"Silent Suffering," in *TIME Magazine*, April 17, 2000.

"Study Shows Lower Rates of Opioid Abuse," in *The Badger Herald*, April 18, 2000.

"Timely Tidbits for April," in *Media Tactics*, April/May 2000.

"Increasing Use of Opioid Analgesics has Not Exacerbated Addiction," in *The Brown University Digest of Addiction Theory and Application*, May 2000.

"Study: More Patients Resorting to Alternative Therapies," in the *Dayton Daily News*, May 9, 2000.

"As Pain Medication Use Increases, Abuse Remains Low," in *Medical Directions*, Summer 2000.

"Literature Abstracts," in *The Network News*, Summer 2000.

"Opioid Analgesia: Medication Use Not Linked to Drug Abuse," in the *APhA Drug Info Line*, June 2000.

"Pain Treatment and Drug Abuse, Apparently Unconnected," in *The New York Times*, July 18, 2000.

"Literature Abstracts," in *The Network News* (Published by Memorial Sloan-Kettering Cancer

Center) Summer 2001, Volume 13

"Use of Narcotic Pain Medication Remains Low as Medical Use Increases," in *PCS Newsletter: News for Fellows of the Philippine College of Surgeons*, August 2000.

"Improving Pain Management," in *Prescriber's Letter*, Vol. 7, No. 9 September 2000.

"Triplicate Prescription Forms in Maine," in *Bangor Daily News*, September 28, 2000.

"Patient Danger Seen in Druggist 'Conscience' Bill," in *The Capital Times*, April 30, 2001.

"Pain Management Policies: An Evaluation," in *State Health Notes*, Vol. 21, Number 336, November 6, 2000.

"Drug Diversion and Dependency," in *Journal of the Pharmacy Society of Wisconsin*, Nov/Dec 2000.

"New Pain Policy Evaluation Guide," in *Your Last Acts Partner Letter*, November-December 2000.

"Regulatory Update," in *Cancer Pain Forum*, Winter 2000, Issue 2.

"Treating Pain is No Simple Matter," in *The Milwaukee Journal Sentinel*, January 8, 2001.

"Spotlight on the Pain & Policy Studies Group," in *The Pain Connection: the Newsletter of the American Pain Foundation*, Spring 2001.

"Playing with Pain Killers," in *Newsweek*, April 9, 2001.

"Study Evaluates Pharmacists' Knowledge of Attitudes Toward Pain Medication Dispensing," in *Nation Boards of Pharmacy Newsletter*, July 2001.

"Program Highlights," in *University of Wisconsin Comprehensive Cancer Center Annual Report 2000-2001.*

"Champion of Change Dr. June Dahl: Her Long Fight for National Pain Management Standards Comes to Fruition," in *Quarterly – The Magazine for University of Wisconsin Medical School Alumni and Friends*, Vol 3, No 2, Spring 2001.

"Regulatory Attitudes Improve, But Fear of Opioid Use Continues," in *The Quality Indicator: Physician Resource*, April 2001.

* "Study of Potential Barriers to Accessing Interventional Pain Management Procedures in Medicare," A study conducted by The Project HOPE Center for Health Affairs for the Medicare Payment Advisory Commission, December 2001.

* "Getting the Relief You Need," in *Seattle Times*, January 2002.

* "The Politics of Managing Pain," in *The States: Regional News of Interest to AARP Members*, January 2002.

* "Doctor Defends Prescribing Powerful Painkillers," in *Charlotte Observer*, February 2002.

Radio Coverage

AMA Radio, April 5, 2000.

World Wide Web Coverage

"Benefits from opioids outweigh risks, study says," *www.cnn.com*.

"Drugs for pain management don't lead to abuse," *www.jointogether.org*.

"Examining opioid use: New hope for terminally ill patients," *www.lastacts.org*.

"Good news on opioids: Use is up, abuse is down," *https://webmd-practice.medcast.com*.

"Increase in opioid analgesia does not necessarily mean increase in abuse," *www.pslgroup.com*. (listserve).

"Increase in opioid analgesia does not necessarily mean increase in abuse," pain_chem_dep@peach.ease.lsoft.com (listserve).

"Increase in opioid analgesic use doesn't necessarily equate to increase in abuse," *www.lastacts.org*.

"More opioid use for pain control does not increase drug abuse," *https://webmd practice.medcast.com*.

"Narcotic painkillers don't raise risk of drug abuse: Prescriptions went up, drug abuse went down," *www.webmd.com*.

"New Guide on Federal and State pain Policy Now Available," *Last Acts Policy Newsletter*, vol 1, issue 6 (email newsletter).

"Opioid use up but abuse waning: Wider availability does not lead to overuse, study finds," *www.healthscout.com*.

"Pain meds do not increase drug abuse," *www.soundpartners.org*.

"Study shows greater morphine-like prescriptions not causing greater abuse," *www.wrn.com*.

"Study shows that abuse of narcotics remains low as medical use increases," *www.lastacts.org*.

* "Nursing home patients' pain underestimated, officials say", in *The Charleston Gazette Online*, www.wvgazette.com.

* ".New Guide on Federal and State Pain Policy Now Available" in *Last Acts Policy Newsletter* – Volume 1, Issue 6, September 2000.

* "New Pain Policy Resource Available" in *BoardNet News* (Federation of State Medical Boards online newsletter, October 13, 2000.

* "PPSG Releases Annual Review of State Pain Policies 2000" in *Last Acts Policy Newsletter*-Volume 2, Issue 2, February 2001.

* "Abuse of Powerful Pain Reliever Rising" in *The Round Up New Mexico State U (U-Wire)*, March 15, 2001.

* "PPSG Annual Review of State Pain Policies Available" in *AACPI update*, March 16, 2001 (listserve).

* "PPSG Study Reports on Pharmacists and Pain Policy" in *Last Acts Policy Newsletter*-Volume 2, Issue 4, April 2001.

*"Regulatory Attitudes Improve, But Fear of Opioid Use Continues" in *Premier Healthcare Resource, Inc.*, April 2001.

"Balancing the response to abuse and diversion of pain medications," pain_chem_dep@peach.ease.lsoft.com (listserve).

"Recent publications of the Pain & Policy Studies Group," pain_chem_dep@peach.ease.lsoft.com (listserve).

"Recent publication from the PPSG re: PMPs," pain_chem_dep@peach.ease.lsoft.com (listserve).

"No relief" in www.salon.com, April 4, 2002 (DJ)

THE
ROBERT WOOD
JOHNSON
FOUNDATION

October 8, 2002

Robert C. Andresen
Administrative Officer
Research and Sponsored Programs
University of Wisconsin-Madison
750 University Avenue, 4th Floor
Madison, WI 53706-1490

Reference: I.D. #036509 - Financial Report Received/No Payment

Dear Mr. Andresen:

This is in reference to your Robert Wood Johnson Foundation grant in support of the Targeted End-of-Life Projects Initiative: a project to assess states' pain policies.

In reviewing your recent financial report, we note that you have overexpended the approved budget categories "Other Direct Subtotal" and "Personnel Subtotal" by more than 5 percent. Please submit a letter which explains these overexpenditures.

Also, in reviewing the final status of this grant, we note that a letter of explanation was requested for the overexpenditures on the "Other Direct Subtotal" per our letter dated October 18, 2001. Please submit this outstanding letter of explanation to the Foundation.

Cumulative expenditures as of April 30, 2002, have been $977,073. The Foundation has made payments to date totaling $761,573 leaving you a cash deficit as of April 30, 2002, of $215,500. We will release your final payment once the letters of explanations are received. Please submit these required letters by October 21, 2002.

If I can assist you further, please contact me at 609-627-5844.

Sincerely,

Sophia Kounelias
Financial Analyst

/SXK

cc: David E. Joranson, M.S.S.W.
Rosemary Gibson

Office of the Vice President and Treasurer

Route 1 and College Road East Post Office Box 2316 Princeton, New Jersey 08543-2316 (609) 452-8701

University of Wisconsin-Madison
Graduate School, Research and Sponsored Programs

September 24, 2002

Sophia Kounelias
Financial Analyst
The Robert Wood Johnson Foundation
Route 1 and College Road East
P. O. Box 2316
Princeton, N J 08543-2316

In reply, please refer to
UW Acct No. 133-CW36

RE: Grant # 036509

Dear Ms. Kounelias:

Enclosed is the final financial report for Year 3 on the above-referenced grant for the period February 1, 2002 through April 30, 2002 under the direction of David Joranson in the Pain and Policy Studies Group at the University of Wisconsin-Madison.

Total expenditures for this project were $977,070.35. The total award amount was $998,000.00. The University of Wisconsin has received $761,573.00 from the Robert Wood Johnson Foundation for this grant. Once our final report has been reviewed, would you please release the final payment of $215,497.35.

Thank you for your support of this project. If you have any questions regarding this report, please contact me at 608/262-9028.

Sincerely,

Mary C. Koscielniak

Mary C. Koscielniak
Accountant

Enclosure
Cc: Joranson, David - Med Schl Pain Study
Kline, Janet - Med Schl Pain Study
Medical School Fiscal Services
File

400 A.W. Peterson Building
750 University Avenue
Madison, WI 53706-1490

Telephone (608) 262-3822
Fax (608) 262-5111
Home Page http://www.rsp.wisc.edu

FINANCIAL REPORT
The Robert Wood Johnson Foundation
P.O. Box 2316
Princeton, NJ 08543-2316
Phone: (609) 452-8701 Fax: (609) 452-9564

UW Account #133-CW36

FA: SXK PA: JMS PO: RG
Project Director: David E. Joranson (608-263-7662)
Fiscal Officer: Robert C. Andresen (608-262-2896)

Grantee: **University of Wisconsin-Madison**
Grant Number: 036509 for (EOL)
Budget Period: Aug-01-2001 to Apr-30-2002
Grant Period: Aug-01-1999 to Apr-30-2002

Budget for Year: 3
Revised: Apr-29-2002

Item	Approved Budget Amount	Period 1 8/01 - 1/02	Period 2 2/02 - 4/02	Total	Variance
		EXPENDITURES			
PERSONNEL					
Project Director	24,435.00	28,300.40	14,075.43	42,375.83	(17,940.83)
Co-Director	11,230.00	11,962.44	6,147.05	18,109.49	(6,879.49)
Project Advisor	3,031.00	3,095.62	-	3,095.62	(64.62)
Project Analyst	9,163.00	9,774.73	4,860.51	14,635.24	(5,472.24)
Res Program Manager	12,732.00	9,845.49	6,103.65	15,949.14	(3,217.14)
Info Processing Cons	9,981.00	5,119.29	-	5,119.29	4,861.71
Assoc Rsch Spec	6,848.00	7,549.49	3,911.25	11,460.74	(4,612.74)
Outreach Specialist	8,989.00	5,625.00	3,375.00	9,000.00	(11.00)
Program Assistant	5,964.00	8,304.92	4,088.58	12,393.50	(6,429.50)
Office Assistant	2,805.00	2,012.76	877.72	2,890.48	(85.48)
Fringe Benefits	31,998.00	29,733.09	14,340.65	44,073.74	(12,075.74)
Personnel Subtotal	127,176.00	121,323.23	57,779.84	179,103.07	(51,927.07)
OTHER DIRECT COSTS					
Supplies	933.00	926.00	-	926.00	7.00
Computer Supplies	250.00	270.00	-	270.00	(20.00)
Duplicating/Printing	2,864.00	2,586.54	-	2,586.54	277.46
Telephone	1,077.00	1,206.71	-	1,206.71	(129.71)
Postage	750.00	750.00	-	750.00	-
Service Agreements	1,500.00	716.25	-	716.25	783.75
Software	3,250.00	3,380.06	2,559.94	5,940.00	(2,690.00)
Travel	5,700.00	7,408.91	-	7,408.91	(1,708.91)
Other Direct Subtotal	16,324.00	17,244.47	2,559.94	19,804.41	(3,480.41)
INDIRECT COSTS	12,915.00	12,471.09	5,430.58	17,901.67	(4,986.67)
CONSULTANT/CONTRACTUAL					
Cons/Contrct Subtotal	20,250.00	-	2,000.00	2,000.00	18,250.00
Grand Total	**176,665.00**	**151,038.79**	**67,770.36**	**218,809.15**	**(42,144.15)**

UW of overexpenditure required.

SXK 10/4/02
Robert C. Andresen
Robert C. Andresen, Administrative Officer

P-43071_00196

THE
ROBERT WOOD
JOHNSON
FOUNDATION

RG
JMS

1
3
EOL

November 21, 2002

Robert C. Andresen
Administrative Officer
Research and Sponsored Programs
University of Wisconsin-Madison
750 University Avenue, 4th Floor
Madison, WI 53706-1490

Reference: I.D. #036509 - Final Financial Report Received/Closure of Grant

Dear Mr. Andresen:

This is in reference to your Robert Wood Johnson Foundation grant in support of the Targeted End-of-Life Projects Initiative: a project to assess states' pain policies.

Your final financial report indicates that as of April 30, 2002, you have had cumulative expenditures of $965,493. The Foundation has remitted payments to date totaling $761,573 leaving you a cash deficit of $203,920. Enclosed with this letter is our final payment in the amount of $203,920.

This completes your financial reporting obligations with respect to this grant. We are glad we were able to assist you in this important endeavor.

Sincerely,

Sophia Kounelias
Financial Analyst

/SXK
Enclosure

cc: David E. Joranson, M.S.S.W.
Rosemary Gibson

University of Wisconsin-Madison
Graduate School, Research and Sponsored Programs

Fax Cover Sheet

To: **Sophia Kounelias**
Company: Robert Wood Johnson Foundation
Telephone: 609-627-5844
Fax: 609-627-6416

From: **Mary C Koscielniak**
Date: 11/11/2002
Total Pages: 4
Subject: Grant # 036509

Comments:

Attached is a revised financial report for year 2 on this grant, along with my cover letter and the Department's letter of explanation for the overexpenditures in software and travel and a reduction of expenses in supplies, telephone and postage.

The original signed letters and report will be mailed to you today. Thank you for your patience and assistance in this matter.

400 A.W. Peterson Building
750 University Avenue
Madison, WI 53706-1490

Telephone (608) 262-3822
Fax (608) 262-5111
Home Page http://www.rsp.wisc.edu/

University of Wisconsin-Madison
Graduate School, Research and Sponsored Programs

November 11, 2002

Sophia Kounelias
Financial Analyst
The Robert Wood Johnson Foundation
Route 1 and College Road East
P. O. Box 2316
Princeton, N J 08543-2316

In reply, please refer to
UW Acct No. 133-CW36

RE: Grant # 036509

Dear Ms. Kounelias:

Enclosed is the revised annual financial report for Year 2 on the above-referenced grant for the period August 1, 2001 through July 31, 2002 under the direction of David Joranson. This is in response to your previous request for the year 2 rebudgeting and justification for overexpenditures.

The Department has prepared a letter of explanation for the travel and software expenditures over budget. The supplies, telephone and postage expenses have been reduced. Their letter is enclosed.

Total revised expenditures for this project were $965,491.55. The University has received $761,573.00 from the Robert Wood Johnson Foundation for this grant. Would you please release the final payment of $203,918.55 when your review of this report has been completed.

Thank you for your support of this project. If you have any questions regarding this report, please contact me at 608/262-9028.

Sincerely,

Mary C. Koscielniak

Mary C. Koscielniak
Accountant

Enclosure
Cc: Joranson, David - Med Schl Pain Study
Kline, Janet - Med Schl Pain Study
Medical School Fiscal Services
File

400 A.W. Peterson Building
750 University Avenue
Madison, WI 53706-1490

Telephone (608) 262-3822
Fax (608) 262-5111
Home Page http://www.rsp.wisc.edu

REVISED FINANCIAL REPORT
The Robert Wood Johnson Foundation
P.O. Box 2316
Princeton, NJ 08543-2316
Phone: (609) 452-8701 Fax: (609) 452-9564

UW Account #133-CW38

FA: SXK PA: JMS PO: RG
Project Director: David E. Joranson (608-263-7662)
Fiscal Officer: Robert C. Andresen (608-262-2696)

Grantee: **University of Wisconsin-Madison**
Grant Number: 036509 for (EOL)
Budget Period: Aug-01-2000 to Apr-30-2001
Grant Period: Aug-01-1999 to Apr-30-2002

Budget for Year: 2
Revised:

EXPENDITURES

Item	Approved Budget Amount	Period 1 8/00 - 1/01	Period 2 2/01 - 07/01	Total	Variance
PERSONNEL					
Project Director	46,104.00	22,710.78	24,328.06	47,038.84	(934.84)
Co-Director	21,189.00	13,809.36	13,425.76	27,235.12	(6,046.12)
Project Advisor	5,718.00	2,925.00	2,925.00	5,850.00	(132.00)
Project Analyst	17,288.00	9,398.76	9,398.76	18,797.52	(1,509.52)
Res Program Manager	24,022.00	11,808.00	9,840.00	21,648.00	2,374.00
Info Processing Cons	18,833.00	9,305.52	9,305.52	18,611.04	221.96
Assoc Rsch Spec	12,921.00	9,618.00	9,160.00	18,778.00	(5,857.00)
Outreach Specialist	16,960.00	7,417.26	8,241.39	15,658.65	1,301.35
Program Assistant	11,252.00	2,927.98	7,102.16	10,030.14	1,221.86
Office Assistant	5,292.00	3,812.02	3,922.80	7,734.82	(2,442.82)
Fringe Benefits	60,372.00	29,632.78	31,296.09	60,928.87	(556.87)
Personnel Subtotal	239,951.00	123,365.46	128,945.54	252,311.00	(12,360.00)
OTHER DIRECT COSTS					
Supplies	2,700.00	249.05	2,296.17	2,545.22	154.78
Computer Supplies	500.00	295.12	239.20	534.32	(34.32)
Duplicating/Printing	2,865.00	10.00	694.75	704.75	2,160.25
Telephone	2,155.00	44.47	1,353.33	1,397.80	757.20
Postage	1,500.00	1,365.69	180.02	1,545.71	(45.71)
Service Agreements	3,500.00	1,481.82	-	1,481.82	2,018.18
Software	6,500.00	4,264.01	4,244.94	8,508.95	(2,008.95)
Travel	15,960.00	18,337.86	9,049.96	27,387.82	(11,427.82)
Other Direct Subtotal	35,180.00	26,048.02	18,058.37	44,106.39	(8,926.39)
INDIRECT COSTS	24,762.00	13,447.21	13,230.35	26,677.56	(1,915.56)
CONSULTANT/CONTRACTUAL					
Cons/Contrct Subtotal	44,000.00	15,295.50	3,741.40	19,036.90	24,963.10
Grand Total	**343,893.00**	**178,156.19**	**163,975.66**	**342,131.85**	**1,761.15**

SXK 11/21/01

Robert C. Andresen, Administrative Officer

PAIN & POLICY STUDIES GROUP

WHO Collaborating Center
for Policy and Communications
in Cancer Care

November 7, 2002

Sophia Kounelias, Financial Analyst
Robert Wood Johnson Foundation
Route 1 and College Road East
Post Office Box 2316
Princeton, NJ 08543-2316

Reference: RWJF # 036509, UW # 133-CW36

Dear Ms. Kounelias:

I am writing to explain the overexpenditures in the Other Direct Costs category for Year 2 (August 2000 through July 2001) of the above referenced grant. Because I started as the Program Administrator in June 2002, I was unfamiliar with the expenditures made during Year 2. However, after reviewing the Other Direct Costs expenditures, it seemed to me that several of the line items were inappropriate (Supplies, Telephone, Postage) and I have transferred the expenditures accordingly, see table below.

Other Direct Costs	Budget	Expenditure	Transfer	Revised	Variance
Supplies	$2,700.00	$9,182.59	($6,637.37)	$2,545.22	$154.78
Computer Supplies	$500.00	$534.32	$0.00	$534.32	($34.32)
Duplicating/Printing	$2,865.00	$704.75	$0.00	$704.75	$2,160.25
Telephone	$2,155.00	$4,492.36	($3,094.56)	$1,397.80	$757.20
Postage	$1,500.00	$2,436.53	($890.82)	$1,545.71	($45.71)
Service Agreements	$3,000.00	$1,481.82	$0.00	$1,481.82	$1,518.18
Software	$6,500.00	$8,508.95	$0.00	$8,508.95	($2,008.95)
Travel	$15,960.00	$27,387.82	$0.00	$27,387.82	($11,427.82)
Other Direct Costs Total	$35,180.00	$54,729.14	($10,622.75)	$44,106.39	($8,926.39)

As for the other two overexpenditures: The Software expenditure reflects the actual costs of a subscription to LexisNexis online service ($540/month), plus annual educational site licenses (WordPerfect, SPSS, Paradox, Groupwise, Reference Manager, and Teleform) for project staff. The original Travel budget was for expenses for project staff to attend various scientific meetings/conferences such as American Pain Society, Pain Management and Chemical Dependency, State Cancer Pain Initiative, and State Community Partnerships to present research data/products. The Travel overexpenditure occurred for two reasons. One, project staff attended additional meetings, including American Society for Law, Medicine, and Ethics, and National Association of State Controlled Substances Authorities. Two, the original Travel budget underestimated the cost of the trips, which were for 3-4 nights each, and included registration fees, plane fare, lodging, meals, and ground transportation.

I hope that this explanation meets with the approval of the Foundation.

Sincerely,

Janet Kline

Janet Kline
Program Administrator

SECTION

10

SITE VISITS

ITEM

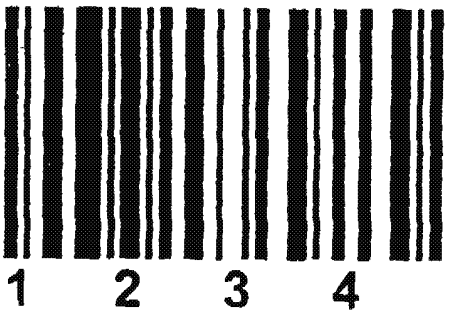
NOT

SUBMITTED

SECTION

11

CONSULTANT REPORTS



ITEM

NOT

SUBMITTED

SECTION

12

PRESS COVERAGE, BROCHURES, ETC...

PAIN & POLICY STUDIES GROUP

WHO Collaborating Center
for Policy and Communications
in Cancer Care

PRESS RELEASE

Contact: Kim Solberg
(608)262-9272

ABUSE OF NARCOTIC[1] PAIN MEDICATIONS REMAINS LOW AS MEDICAL USE INCREASES

Madison, WI – An article published in the April 5th *Journal of the American Medical Association* (JAMA) challenges the conventional wisdom that drugs used for relief of severe pain—such as morphine--are widely abused. The work was done by the Pain & Policy Studies Group (PPSG) of the University of Wisconsin Comprehensive Cancer Center.

First, the study found that from 1990 to 1996 there were significant increases in the amounts of opioids such as morphine prescribed by physicians in the U.S. (Morphine and other opioids are medically essential for the relief of severe pain and are approved for medical use by prescription only.) "Although there are many ways to treat pain, the increased medical use of opioids is a strong indicator that we are making progress to improve pain management," said David E. Joranson, lead author and Director of the PPSG.

Second, the study found that abuse of opioids was low and stable, accounting for a small part (less than 5%) of the national drug abuse problem, as measured by drug overdoses. (Opioids have a potential for abuse and are controlled under federal and state law as controlled substances.) From 1990 to 1996 abuse of opioids increased 6.6 % in contrast to the abuse of the category illicit drugs, including cocaine and heroin which increased by 109 %. "At a time when abuse of illicit drugs continues to increase, it is reassuring that abuse of opioid pain medications is a small part of the U.S. drug problem," said Joranson.

One of the reasons for inadequate pain management is that health professionals fear that opioid medications will be abused. Co-author Karen Ryan, Chief Policy Analyst for the PPSG, said "This study suggests that increased use of opioid pain medications resulting in abuse may be based more on myth than reality. This is exceptionally good news for pain patients and for public health officials."

-more-

[1]"Narcotic" is an old legal term which is being replaced by the modern medical term "opioid."

According to Joranson, "However, we must continue to exercise caution with opioids, since there is an illicit demand for these drugs. Health care professionals and patients should continue to exercise appropriate care to avoid diversion and abuse of pain medications."

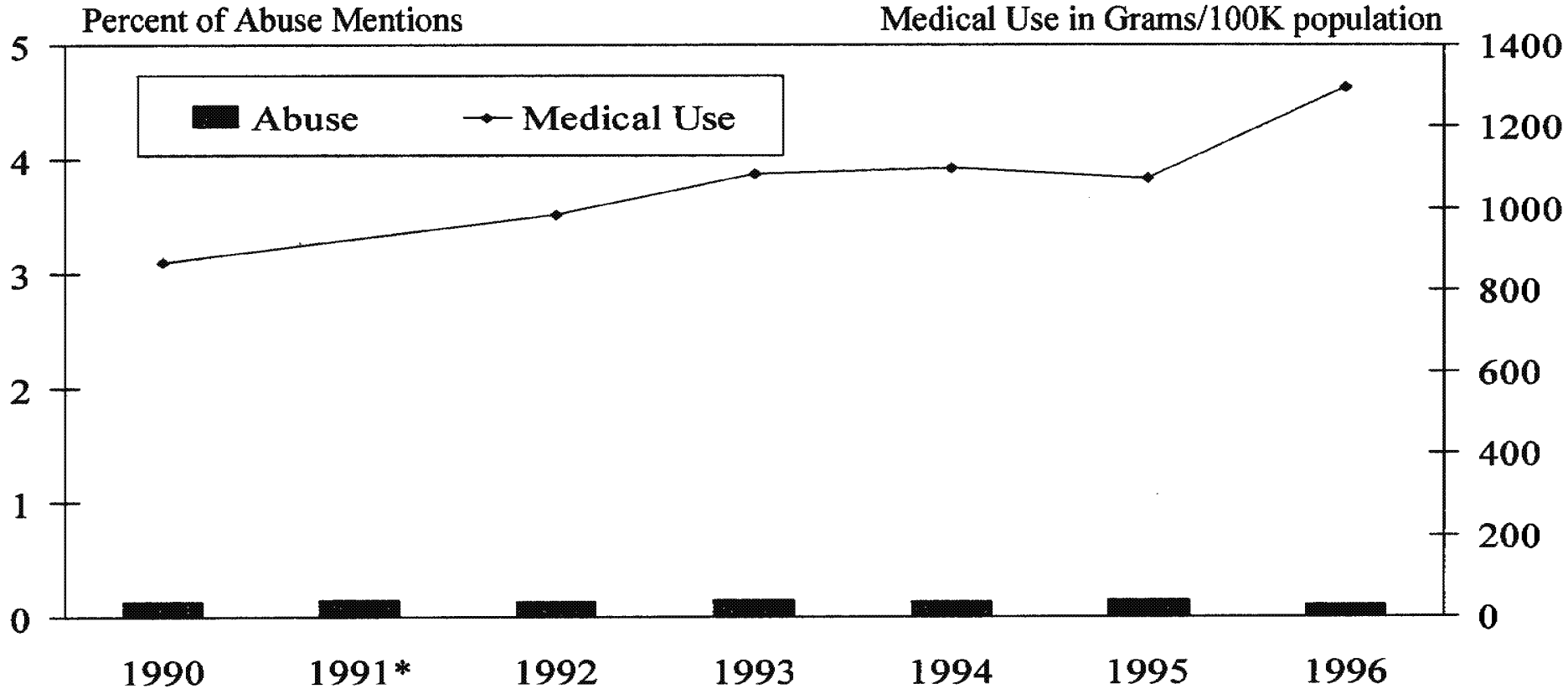
According to Ms. Ryan, "These results indicate that the U.S. could be a model for how to achieve a balanced controlled substances policy, that is, one which can improve the availability of opioids for medical purposes while limiting abuse."

The article, titled "Trends in Medical Use and Abuse of Opioid Analgesics," examined data from two sources sponsored by the federal government: 1) medical use data from the Automation of Reports and Consolidated Orders System (U.S. Drug Enforcement Administration) that collects information on the national distribution of selected drugs to pharmacies and hospitals, and 2) abuse data from the Drug Abuse Warning Network (Substance Abuse and Mental Health Services Administration) that collects data about drug overdoses from a nationally representative sample of general hospital emergency departments.

For more information about the JAMA article, the Pain & Policy Studies Group, federal and state pain-related policies, and a variety of resources about pain and policy, contact **http://www.medsch.wisc.edu/painpolicy**. The Pain & Policy Studies Group is a World Health Organization Collaborating Center for Policy and Communications in Cancer Care. Its mission is the study of public policy in relation to pain management. The PPSG program of policy research, development, and education is funded primarily by the Robert Wood Johnson Foundation.

-more-

Medical Use and Abuse of Morphine in the US



This graphic presents trend information from 1990 to 1996 about morphine use and abuse. The information comes from two data systems that are maintained by the federal government, DAWN and ARCOS (described in the press release). The graphic shows that the abuse of morphine (one of the opioid analgesics used for severe pain) remained very low and stable, while the medical use of morphine increased substantially.

*1991 Medical use (ARCOS) data interpolated due to incomplete reporting.
Source: U.S. Drug Enforcement Administration & SAMHSA Drug Abuse Warning Network.
By: Pain & Policy Studies Group, University of Wisconsin/WHO Collaborating Center, 1999.

Targeted End-of-Life Projects Initiative
"Building Capacity to Promote Pain Policy Through Evaluation, Research and Communication"
Grant # 036509

Special Article

Pain Management and Prescription Monitoring

David E. Joranson, MSSW; Grant M. Carrow, PhD; Karen M. Ryan, MA; Linda Schaefer; Aaron M. Gilson, PhD; Patricia Good; John Eadie, MA; Susan Peine; June L. Dahl, PhD

Pain & Policy Studies Group, University of Wisconsin Comprehensive Cancer Center (DEJ, KMR, AMG), Madison, WI, USA; Massachusetts Department of Public Health, Drug Control Program (GMC), Jamaica Plain, MA, USA; Texas Department of Public Safety (LS), Austin, TX, USA; U.S. Drug Enforcement Administration, Office of Diversion Control (PG, SP), Arlington, VA, USA; Wadsworth Center for Laboratories & Research, Department of Health (JE), Albany, NY, USA; Department of Pharmacology, University of Wisconsin (JLD), Madison, WI, USA

Address reprint requests to:
David E. Joranson, MSSW
Pain & Policy Studies Group, 1900 University Avenue,
Madison, WI 53705-4013
Tel: (608)263-7662
Fax: (608)263-0259

Funded by the Robert Wood Johnson Foundation

Pain Management and Prescription Monitoring

Abstract

Preventing diversion and abuse of prescription controlled substances while ensuring their availability for legitimate medical use is an important public health goal in the United States. In one approach to preventing and identifying drug diversion, seventeen states have implemented prescription monitoring programs (PMPs) to monitor the prescribing of certain controlled substances. While PMPs are not intended to interfere with legitimate prescribing, some in the pain management community feel that they negatively affect prescribing for pain management. This article describes a collaborative project initiated by the Pain & Policy Studies Group which brought together regulatory and pain management representatives twice in 1998 to share perspectives and reconcile differing views on the effects of PMPs. The ultimate goals of this project are to provide accurate information to healthcare clinicians about PMPs, better define the balance between preventing drug diversion and providing pain management, and promote continued dialog and cooperation among the groups.

Key words: prescription monitoring programs, triplicate prescriptions, single-copy serialized prescriptions, multiple copy prescriptions, electronic transmission, pain management, controlled substances, opioid analgesics, drug diversion, prescription drug abuse

Word count: 150

I. Prescription Controlled Substances and Pain

Undertreatment of pain is a major public health issue in the United States.[1-8] There are many safe and effective ways to treat pain. Drug therapy with opioid analgesics plays an important role in pain management and should be available when needed for the treatment of acute pain and chronic cancer, as well as non-cancer, pain.[6,9-14] Clinicians should be knowledgeable about using opioids to treat pain, and should not hesitate to prescribe them when opioids are the best clinical choice of treatment.[15] Since opioids have a potential for abuse, they are controlled substances under federal and state law.[16,17] Practitioners must know and comply with federal and state laws and regulations, and exercise sound professional judgement when prescribing opioid analgesics to minimize diversion and abuse of these drugs.

II. Prescription Controlled Substances, Drug Abuse, and Diversion

The diversion of prescription controlled substances to illicit channels is a public health and safety issue. These medications are diverted in numerous ways, including theft, forgery and counterfeiting of prescriptions; illegal sales of prescriptions and drugs; fraudulent activities that victimize physicians, pharmacies, and patients; and by a small percentage of physicians who write prescriptions indiscriminately because they are dishonest, disabled, deceived, or dated in their practices.[18-20] Misuse and abuse of prescription controlled substances can and does lead to serious health consequences, including "drug dependence, overdose and deaths."[18] There is a need for additional studies to document the amount of opioid analgesics that is diverted from prescriptions, or compare this source of diversion with other sources, such as from pharmacy thefts.[4] The nature and extent of prescription drug abuse has been reported by the Drug Enforcement Administration (DEA),[21] and the abuse trends of opioid analgesics have been evaluated.[22]

III. The Role of Law and Government Agencies

There is no question that it is legal under federal and state law for duly licensed and registered physicians, pharmacists, and nurses to prescribe, dispense, and administer controlled substances for legitimate medical purposes and in the usual course of professional practice. Although all state laws are based on this premise, the provisions may differ from state to state. The National Conference of Commissioners on Uniform State Laws (NCCUSL) provides a model act to which states can refer.[17]

State and federal government agencies respond not only to the diversion and abuse of opioids and other controlled substances, but also to the treatment needs of patients, including those in pain. Regulatory agencies endeavor to ensure that the professionals who care for ill and injured persons are qualified to do so. State governments examine and license healthcare professionals and facilities. The DEA and some states issue controlled substances registrations to state licensed practitioners for prescribing, dispensing, and administering controlled substances. State and federal agencies enforce security and record-keeping to protect the manufacture and supply of opioid medications, while the federal government ensures their continued availability by setting production quotas that satisfy legitimate medical needs. Regulatory agencies also work to reduce drug abuse through substance prevention, treatment programs, and law enforcement. They also investigate and take appropriate action when there is evidence of illegal activity, practitioner impairment, or incompetence.

IV. Evolution of State Prescription Monitoring Programs

It is within this broad context that a number of states have established prescription monitoring programs (PMPs). (Table 1 describes the current status of PMPs in the United States.) Typically, PMPs collect prescribing and dispensing data from pharmacies, conduct review and analysis of the data, and disseminate it to appropriate

regulatory and law enforcement agencies. Following the lead of New York State in the 1910s, California and Hawaii enacted PMPs in the 1940s. By the 1980s, seven more states had added PMPs. These early programs required that physicians use multiple copy forms (duplicate or triplicate) to write prescriptions for Schedule II controlled substances, and that pharmacists send one copy to the state after dispensing a drug. Physicians were usually required to obtain prescription forms from a state agency, and some states charged a fee for the forms. After verifying the practitioner's credentials, the relevant state agency issued the requested forms.

In the 1990s, some states initiated PMPs that rely solely on computer technology to collect data. In these states, a special prescription form is not required. Pharmacies use electronic transmission to enter and transmit electronically to the state the PMP information about controlled substances prescriptions that have been dispensed.

With the advent of recent technological advances, states that used multiple copy prescription forms have modified their PMPs to include an electronic element. In addition, most of these states replaced their multiple copy forms with a single-copy, serially-numbered form (Hawaii and Idaho use duplicate prescription forms with electronic transmission, and California uses triplicate forms concurrently with its electronic transmission system). Rhode Island and Illinois are the only states to completely repeal the requirement to use a special prescription form; both states now use electronic transmission exclusively. A model prescription accountability act, recommended by the National Alliance for Model State Drug Laws and the National Association of State Controlled Substances Authorities (NASCSA), provides for a system that combines electronic monitoring and a serialized prescription form.[23]

In practice, PMPs take different forms because each state government determines the

goals, structure, and organization of its program. Currently, the PMPs are administered by professional boards, health departments, human services agencies, and/or consumer protection agencies, in 12 of the states, and by justice departments, public safety agencies and/or state police in the other five states. The manner in which a program is implemented depends on its stated goals, the mission of the responsible agency, and rules regarding access to the data.

V. Purpose of PMPs

The purpose of PMPs is to reduce the diversion of prescription controlled substances. Objectives of PMPs usually include: (i) education and information; (ii) public health initiatives; (iii) early intervention and prevention of diversion; and (iv) investigations and enforcement.[20] Prescription monitoring is not intended to interfere with medical practice[24] and attempts are made to make it minimally intrusive (e.g., reducing the paperwork burden by replacing multiple copy forms with single-copy serialized forms or eliminating forms altogether). PMPs do not require physicians to obtain prior approval to issue prescriptions, nor do they impose limits on the quantity that may be prescribed. While some state laws limit quantities that can be prescribed in one prescription, such limits are established by laws other than those that establish PMPs.[25] Regulatory agencies that are charged with enforcing the laws with respect to drug diversion also recognize the legitimate need for controlled substances in medical care.[26]

PMPs enable law enforcement investigators to obtain prescription information quickly and efficiently, thereby reducing time and resources that would be otherwise expended in obtaining the information from individual practitioners or pharmacies. PMPs can also provide an efficient means of handling complaints, and can result in speedier resolution of pending cases, dismissal of unfounded complaints, and avoidance of unnecessary investigations. Aggregate data on prescribing trends from most PMPs is usually

available for educational and research purposes. In all uses of the data, confidentiality of prescribers, pharmacies, and patients is protected, thereby meeting another goal of PMPs.[20]

State agencies indicate that a PMP can have a deterrent effect on potential criminal activities. Early intervention in illegal activities is one of the identified goals of these programs. For example, state authorities report that use of special prescription forms significantly reduces or eliminates prescription forgery. In addition, PMPs are especially useful for identifying "doctor shopping," scams, and illicit prescribing and dispensing. Drug abusers who are identified as doctor shoppers can be directed into drug treatment or prosecuted, depending on the circumstances of the case. PMPs take into account the possibility that persons who seek pain medications may be patients with inadequately treated pain.[27]

VI. Concerns about PMPs

Preventing drug diversion and abuse, and ensuring the availability of drugs for medical purposes, are often perceived as potentially incompatible goals. For example, there has been considerable debate between regulatory and medical groups about the requirement for government-issued prescription forms. During the 1980s and 1990s, representatives of the medical community expressed concerns that these special forms were an intrusion into medical practice and the doctor-patient relationship. They were concerned about being investigated and about the additional administrative burden associated with handling a special form for this class of medication. Federal and state agencies charged with administering controlled substances laws responded that the programs were effective in reducing drug diversion,[15] with minimal impact on legitimate medical practice.[21,24,28]

A number of publications have examined the effect of multiple copy forms on diversion

and/or medical practice.[29-38] The National Institute on Drug Abuse and the Institute of Medicine have called for more definitive research in this area.[33,39] States have worked with their medical communities to address their concerns. States, such as New York and Texas that are replacing multiple copy prescription forms with an official single-copy prescription form and electronic transmission, assert that prescribing on a single-copy form rather than a multiple copy form is intended to be closer to the use of ordinary prescription forms. While single-copy forms reduce paperwork handling, they retain the ability to prevent prescription forgery and counterfeiting.[19]

Representatives of the Alliance of States with Prescription Monitoring Programs ("the Alliance"), the states with PMPs, and the DEA stress to physicians that prescription monitoring data cannot and do not serve as *prima facie* evidence of illicit activities. PMP data can provide an indication of a possible problem that may require further inquiry. Further, the PMP administrators stress that it is their intention that PMPs be used to enforce state laws in a manner that is most supportive of, and least disruptive to, medical and pharmacy practice.

VII. Collaboration Between Pain Management and Regulatory Groups

In 1998, the University of Wisconsin Pain & Policy Studies Group (PPSG) initiated a collaborative project with the DEA, the Alliance, and the Analgesic Regulatory Affairs Committee of the American Pain Society (APS) in order to exchange perspectives on PMPs and the prescribing of opioids for pain management. The goal of the project was to explore how the groups could cooperate to assure appropriate care for patients in pain, while protecting the public from diversion of opioids to non-medical, illicit use. The immediate objectives were to:

- enhance cooperation between the DEA, state PMPs, and the pain management

community,

- better define the balance between the provision of opioid analgesic treatment to patients in pain and prevention of diversion of opioids into non-medical, illicit use, and

- provide information on these issues to the professionals who care for patients and administer controlled substances laws.

VIII. Meetings

The PPSG organized two meetings to bring together individuals from these groups. The first meeting was held at the University of Wisconsin in Madison, Wisconsin, on July 20-21, 1998. Fifteen people were invited; thirteen were able to attend.[A] The meeting began with a discussion of the perspectives held by each of the attendees. Following the exchange, it was evident to participants that, while there were misconceptions regarding some issues, there was a shared interest in improving pain management and preventing the diversion of prescription controlled substances. The participants prepared a list of the points of agreement.

The initial points of agreement were refined at a second meeting, held in Charleston, South Carolina, on October 29, 1998 during the annual meeting of NASCSA.[B] The nine

[A] The representatives at the July 1998 meeting were: For the Alliance - **Grant Carrow**, Massachusetts Department of Public Health; **John Eadie**, State University of New York; **David Hale**, Oklahoma Bureau of Narcotics; **Linda Schaefer**, Texas Department of Public Safety. For the APS - **June Dahl**, APS Analgesic Regulatory Affairs Committee; **Aaron Gilson**, Pain & Policy Studies Group; **David Haddox**, American Academy of Pain Medicine; **David Joranson**, Pain & Policy Studies Group; **David Mackey**, Mayo Clinic Jacksonville; **Karen Ryan**, Pain & Policy Studies Group. For the DEA - **Patricia Good**, Office of Diversion Control; **Susan Peine**, Office of Diversion Control. Other - **Thomas D. Wyatt, Jr.**, National Association of State Controlled Substances Authorities. Unable to attend were: **William Marcus**, California Deputy Attorney General; **Russell Portenoy**, Beth Israel Medical Center.

[B] The attendees for the October 1998 meeting were: **Grant Carrow**, Massachusetts Department of Public

participants at the second meeting decided to write a jointly-authored article about the collaboration, and to consider future publications regarding PMPs.

The initial perspectives that were offered by the participants provided guidance for subsequent discussions. The group reached consensus on seven issues for which brief descriptions follow; where the consensus involved future action, the progress to date is noted.

IX. Consensus

1) Publications. The participants felt that it is imperative to provide accurate information to educate the medical community about the purpose and operation of PMPs. A jointly-authored article describing the collaboration will be prepared for publication in a medical journal. In addition, information about PMPs will be prepared by the Alliance for dissemination to physicians, pharmacists, nurses, and regulators. Both publications should describe the common goals of the prescription monitoring and pain communities.

> **Progress** This article is a result of the collaboration between the PPSG, the Alliance, the APS, and the DEA. In addition, the Alliance has prepared a document detailing the goals of prescription monitoring.[20] The DEA has compiled information from the states into two publications: "Prescription Accountability Resource Guide"[24] and "Committee Report on Establishing a State Prescription Monitoring Program."[28] The DEA and the National Alliance for Model State Drug Laws have compiled additional information from the states for another publication: "Diversion and Abuse of Prescription Drugs: A Closer Look

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Health; **John Eadie**, State University of New York; **Patricia Good**, Drug Enforcement Administration; **David Hale**, Oklahoma Bureau of Narcotics; **David Joranson**, Pain & Policy Studies Group; **Susan Peine**, Drug Enforcement Administration; **Karen Ryan**, Pain & Policy Studies Group; **Linda Schaefer**, Texas Department of Public Safety; **Thomas D. Wyatt, Jr.**, National Association of State Controlled Substances Authorities.

at State Prescription Monitoring Programs."[21]

2) FSMB Guidelines. Many states have adopted pain policies in recent years. Eight states have adopted the Federation of State Medical Boards (FSMB) "Model Guidelines for the Use of Controlled Substances for the Treatment of Pain."[40] In many states, controlled substance, health, and law enforcement agencies have endorsed the Guidelines.

Progress Representatives at the meeting supported the FSMB's Model Guidelines. They have also been endorsed by the DEA and NASCSA, as well as by the APS and the American Academy of Pain Medicine (AAPM).

3) Resource information. The participants recommended that state and federal officials and the pain management community increase their efforts to exchange information. For example, they advised that pain specialists be available to PMPs to consult on interpretation of data. Regulatory agencies receive calls from patients whose physicians won't prescribe adequate pain medication for them. The pain management community could assist these patients by providing referrals to physicians with appropriate training in pain management. The Alliance can be used as a resource for the pain management community by providing contacts and information on PMPs in general, or on specific states.

Progress General information on PMPs, including state and federal contacts, is available from the Alliance (http://www.nascsa.org/monitoring.htm), and the DEA Diversion Control Program (http://www.deadiversion.usdoj.gov/pubs/program/index.html). In addition, the Alliance and the DEA serve as clearinghouses for specific questions or issues concerning PMPs.

4) Reciprocal meetings. The participants recommended that representatives from the pain management and regulatory and law enforcement communities present and participate in each others' meetings in order to provide information and to address questions and misperceptions. This kind of exchange can increase understanding of mutual goals, provide an opportunity to communicate about issues that arise, and address practitioners' concerns about regulatory oversight.

Progress Representatives of the DEA, the Alliance, and the FSMB have been invited to participate in national and state pain meetings to clarify issues related to prescription controlled substances, PMPs, and medical boards' disciplinary responsibilities. State agencies routinely provide speakers for meetings of their state's medical associations and societies. These presentations have been greatly appreciated by clinicians. NASCSA has invited representatives from the pain field to make presentations at its annual meetings. The groups should continue these cooperative endeavors.

5) Scam alerts. Information on the most recently identified "scams" should be included on the DEA's web page and in the APS Bulletin.

Progress The DEA's website contains recent information on scams being used to procure prescription controlled substances illegally. It is available on the DEA web pages http://www.deadiversion.usdoj.gov/pubs/brochures/drugabuser.htm and http://www.deadiversion.usdoj.gov/pubs/pressrel/dr_scam.htm.

6) Federal policy. Existing DEA policy recognizing the use of opioids for chronic pain should be disseminated more widely in the medical, pharmacy, and nursing communities.

Progress The DEA regulations for prescribing and dispensing controlled substances are available on the following websites: DEA Diversion Control Program (http://www.deadiversion.usdoj.gov/21cfr/cfr/2106cfrt.htm),

Government Printing Office (http://www.access.gpo.gov/nara/cfr/waisidx_00/21cfr1306_00.html), and by link from PPSG (http://www.medsch.wisc.edu/painpolicy). A DEA statement on the use of controlled substances for pain management is being drafted. It will be included in revisions of existing DEA publications about controlled substances for physicians,[15] pharmacists,[41] and nurses,[42] and will be included on its website: http://www.deadiversion.usdoj.gov/pubs/manuals/index.html. PPSG presentations generally include information about federal policy and informational resources.

7) **Data**. In keeping with state regulations, data from PMPs should be available to researchers to evaluate current trends in prescribing and the effectiveness of educational programs.

Progress Data from prescription monitoring programs are available in the publications listed in item 1. Other projects that make use of PMP data, including university-sponsored research, are underway in various states. Educational facilities, pain management groups, and other specialty groups may find PMP data useful in evaluating treatment trends and the effectiveness of educational programs on pain management.

X. Conclusion

Representatives from pain management and prescription monitoring groups have recognized the importance of information exchange and cooperation. Since the meetings began in 1998, these groups have taken several important steps to increase cooperation and understanding and to nurture a mutual respect for the goals of each discipline. With continued activity expected in the states to improve pain management and address drug diversion, it is essential to continue these efforts to provide accurate information and

promote communication and understanding between the groups involved.

Providing adequate pain management and preventing diversion and abuse of prescription controlled substances are both important public health goals. Achieving both goals requires exchange of information and perspectives, identification of issues, and concerted action. Increased communication and cooperation between regulatory and pain groups can contribute to a good balance between drug control and drug availability.

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Table 1. States with Prescription Monitoring Programs

STATE	YEAR OF PROGRAM ENACTMENT	PROGRAM TYPE	SCHEDULES/ DRUGS COVERED	INITIAL PROGRAM TYPE	YEAR OF INITIAL PROGRAM ENACTMENT
CALIFORNIA	1996	TRIPLICATE/ELECTRONIC	C-II	TRIPLICATE	1939
HAWAII	1996	DUPLICATE ELECTRONIC	C-II C-II, III, IV	DUPLICATE	1943
IDAHO	1997	DUPLICATE ELECTRONIC	C-II C-II, III, IV	TRIPLICATE	1967
ILLINOIS	1999	ELECTRONIC	C-II	TRIPLICATE	1961
INDIANA	1994	SINGLE-COPY/ELECTRONIC	C-II, III, IV, V	TRIPLICATE	1987
KENTUCKY	1998	ELECTRONIC	C-II, III, IV, V		
MASSACHUSETTS	1992	ELECTRONIC	C-II		
MICHIGAN	1993	SINGLE-COPY, SERIALIZED/ ELECTRONIC	C-II	TRIPLICATE	1988
NEVADA	1995	ELECTRONIC	C-II, III, IV		
NEW MEXICO	1994	ELECTRONIC	C-II		
NEW YORK	1998	SINGLE-COPY, SERIALIZED/ ELECTRONIC	C-II AND BENZODIAZEPINES	TRIPLICATE	1972
OKLAHOMA	1990	ELECTRONIC	C-II		
RHODE ISLAND	1997	ELECTRONIC	C-II, III	DUPLICATE	1978
TEXAS	1997	SINGLE-COPY, SERIALIZED/ ELECTRONIC	C-II	TRIPLICATE	1981
UTAH	1995	ELECTRONIC	C-II, III, IV, V		
WASHINGTON	1984	TRIPLICATE	C-II, III, IV, V		
WEST VIRGINIA	1995	ELECTRONIC	C-II		

NOTE: CURRENT AS OF 10/30/00; PRESCRIPTION MONITORING PROGRAMS ARE SUBJECT TO CHANGE. SOURCES: DRUG ENFORCEMENT ADMINISTRATION, "PRESCRIPTION ACCOUNTABILITY RESOURCE GUIDE," SEPTEMBER 1998; AND UPDATED INFORMATION OBTAINED FROM STATES.

REFERENCES

(1) WOLFE J, GRIER HE, KLAR N, ET AL. SYMPTOMS AND SUFFERING AT THE END OF LIFE IN CHILDREN WITH CANCER. N ENGL J MED. 2000;342(5):326-333.

(2) BERNABEI R, GAMBASSI G, LAPANE K, ET AL. MANAGEMENT OF PAIN IN ELDERLY PATIENTS WITH CANCER. JAMA. 1998;279(23):1877-1882.

(3) CLEELAND CS, GONIN R, BAEZ L, LOEHRER P, PANDYA KJ. PAIN AND TREATMENT OF PAIN IN MINORITY PATIENTS WITH CANCER. ANN INTERN MED. 1997;127:813-816.

(4) INSTITUTE OF MEDICINE COMMITTEE ON CARE AT THE END OF LIFE. APPROACHING DEATH: IMPROVING CARE AT THE END OF LIFE. WASHINGTON, D.C.: NATIONAL ACADEMY PRESS, 1997.

(5) SUPPORT STUDY PRINCIPAL INVESTIGATORS. A CONTROLLED TRIAL TO IMPROVE CARE FOR SERIOUSLY ILL HOSPITALIZED PATIENTS: THE STUDY TO UNDERSTAND PROGNOSES AND PREFERENCES FOR OUTCOMES AND RISKS OF TREATMENTS (SUPPORT). JAMA. 1995;274(20):1591-1598.

(6) JACOX A, CARR DB, PAYNE R, ET AL. MANAGEMENT OF CANCER PAIN. IN: CLINICAL PRACTICE GUIDELINE NUMBER 9. ROCKVILLE, MD: AGENCY FOR HEALTH CARE POLICY AND RESEARCH, U.S. DEPT OF HEALTH AND HUMAN SERVICES, PUBLIC HEALTH SERVICE, 1994. AHCPR PUBLICATION 94-0592.

(7) CLEELAND CS, GONIN R, HATFIELD AK, ET AL. PAIN AND ITS TREATMENT IN OUTPATIENTS WITH METASTATIC CANCER. N ENGL J MED. 1994;330(9):592-596.

(8) AMERICAN PAIN SOCIETY. PRINCIPLES OF ANALGESIC USE IN THE TREATMENT OF ACUTE PAIN AND CANCER PAIN. FOURTH ED. GLENVIEW, ILL: AMERICAN PAIN SOCIETY, 1999.

(9) ACUTE PAIN MANAGEMENT GUIDELINE PANEL. ACUTE PAIN MANAGEMENT: OPERATIVE OR MEDICAL PROCEDURES AND TRAUMA. IN: CLINICAL PRACTICE GUIDELINE. ROCKVILLE, MD: AGENCY FOR HEALTH CARE POLICY AND RESEARCH, U.S. DEPT OF HEALTH AND HUMAN SERVICES, PUBLIC HEALTH SERVICE, 1992. AHCPR PUBLICATION 92-0032.

(10) PORTENOY RK. OPIOID THERAPY FOR CHRONIC NONMALIGNANT PAIN: CLINICIAN'S PERSPECTIVE. J LAW MED ETHICS. 1996;24(4):296-309.

(11) WORLD HEALTH ORGANIZATION. CANCER PAIN RELIEF. GENEVA, SWITZERLAND: WORLD HEALTH ORGANIZATION, 1986.

(12) LEVY MH. PHARMACOLOGIC TREATMENT OF CANCER PAIN. N ENGL J MED. 1996;335:1124-1132.

(13) DOYLE D, HANKS G, MACDONALD N. OXFORD TEXTBOOK OF PALLIATIVE MEDICINE. NEW YORK, NY: OXFORD UNIVERSITY PRESS, 1993.

(14) PAPPAGALLO M, HEINBERG LJ. ETHICAL ISSUES IN THE MANAGEMENT OF CHRONIC NONMALIGNANT PAIN. SEMIN NEUROL. 1997;17:203-211.

(15) DRUG ENFORCEMENT ADMINISTRATION. PHYSICIAN'S MANUAL: AN INFORMATIONAL OUTLINE OF THE CONTROLLED SUBSTANCES ACT OF 1970. WASHINGTON, D.C.: U.S. DEPARTMENT OF JUSTICE, 1990.

(16) CONTROLLED SUBSTANCES ACT OF 1970. PUB L NO. 91-513, 84 STAT 1242.

(17) NATIONAL CONFERENCE OF COMMISSIONERS ON UNIFORM STATE LAWS. UNIFORM CONTROLLED SUBSTANCES ACT. NCCUSL; CHICAGO, IL. ADOPTED AT ITS ANNUAL CONFERENCE MEETING IN ITS ONE-HUNDRED-AND-THIRD-YEAR; CHICAGO, IL; JULY 29-AUGUST 5, 1994.

(18) AMERICAN MEDICAL ASSOCIATION. CURTAILING PRESCRIPTION DRUG ABUSE WHILE PRESERVING THERAPEUTIC USE: AMERICAN MEDICAL ASSOCIATION RECOMMENDATIONS FOR DRUG CONTROL POLICY. IN: WILFORD BB, ED. BALANCING THE RESPONSE TO PRESCRIPTION DRUG ABUSE. CHICAGO, IL: AMERICAN MEDICAL ASSOCIATION; 1990:273-298.

(19) NEW YORK STATE PUBLIC HEALTH COUNCIL. BREAKING DOWN THE BARRIERS TO EFFECTIVE PAIN MANAGEMENT: RECOMMENDATIONS TO IMPROVE THE ASSESSMENT AND TREATMENT OF PAIN IN NEW YORK STATE. ALBANY, NY: NEW YORK STATE DEPARTMENT OF HEALTH, 1998.

(20) ALLIANCE OF STATES WITH PRESCRIPTION MONITORING PROGRAMS. THE GOALS OF PRESCRIPTION MONITORING. JAMAICA PLAIN, MA: MASSACHUSETTS DEPARTMENT OF HEALTH, DRUG CONTROL PROGRAM, 1999. (CAN BE ACCESSED AT HTTP://WWW.NASCSA.ORG/MONITORING.HTM)

(21) DRUG ENFORCEMENT ADMINISTRATION, NATIONAL ALLIANCE FOR MODEL STATE DRUG LAWS. DIVERSION AND ABUSE OF PRESCRIPTION DRUGS: A CLOSER LOOK AT STATE PRESCRIPTION MONITORING PROGRAMS. WASHINGTON, D.C.: DRUG ENFORCEMENT ADMINISTRATION, 2000. (CAN BE ACCESSED AT HTTP://WWW.DEADIVERSION.USDOJ.GOV/PUBS/PROGRAM/RX_MONITOR/INDEX.HTML)

(22) JORANSON DE, RYAN KM, GILSON AM, DAHL JL. TRENDS IN MEDICAL USE AND ABUSE OF OPIOID ANALGESICS. JAMA. 2000;283(13):1710-1714.

(23) NATIONAL ASSOCIATION OF STATE CONTROLLED SUBSTANCES AUTHORITIES. MODEL PRESCRIPTION ACCOUNTABILITY ACT. COLONIAL WILLIAMSBURG, VA; NOVEMBER 2, 1996: NATIONAL ASSOCIATION OF STATE CONTROLLED SUBSTANCES AUTHORITIES. (CAN BE ACCESSED AT HTTP://WWW.NASCSA.ORG/MONITORING.HTM)

(24) DRUG ENFORCEMENT ADMINISTRATION - OFFICE OF DIVERSION CONTROL. PRESCRIPTION ACCOUNTABILITY RESOURCE GUIDE. WASHINGTON, D.C.: DRUG ENFORCEMENT ADMINISTRATION, 1998. (CAN BE ACCESSED AT HTTP://WWW.DEADIVERSION.USDOJ.GOV/PUBS/PROGRAM/RX_ACCOUNT/INDEX.HTML)

(25) JORANSON DE, GILSON AM, RYAN KM, ET AL. ACHIEVING BALANCE IN FEDERAL AND STATE PAIN POLICY: A GUIDE TO EVALUATION. MADISON, WISCONSIN: PAIN & POLICY STUDIES GROUP, UNIVERSITY OF WISCONSIN COMPREHENSIVE CANCER CENTER, 2000. (CAN BE ACCESSED AT HTTP://WWW.MEDSCH.WISC.EDU/PAINPOLICY/EGUIDE2000/INDEX.HTML)

(26) NATIONAL ASSOCIATION OF STATE CONTROLLED SUBSTANCES AUTHORITIES. NASCSA RESOLUTION 99-01. A RESOLUTION ENDORSING THE MODEL GUIDELINES FOR THE USE OF CONTROLLED SUBSTANCES FOR THE TREATMENT OF PAIN. ADOPTED AT THE NASCSA 15TH ANNUAL EDUCATIONAL CONFERENCE; COEUR D'ALENE, IDAHO; OCTOBER 29, 1999. (CAN BE ACCESSED AT HTTP://WWW.NASCSA.ORG/RESOLUTIONS/RES9901.HTM)

(27) WEISSMAN DE, HADDOX JD. OPIOID PSEUDOADDICTION--AN IATROGENIC SYNDROME. PAIN. 1989;36:363-366.

(28) DRUG ENFORCEMENT ADMINISTRATION - OFFICE OF DIVERSION CONTROL. COMMITTEE REPORT ON ESTABLISHING A STATE PRESCRIPTION MONITORING PROGRAM. WASHINGTON, D.C.: DRUG ENFORCEMENT ADMINISTRATION, 1995.

(29) SIGLER KA, GUERNSEY BG, INGRIM NB, ET AL. EFFECT OF A TRIPLICATE PRESCRIPTION LAW ON PRESCRIBING OF SCHEDULE II DRUGS. AM J HOSP PHARM. 1984;41:108-111.

(30) BERINA LF, GUERNSEY BG, HOKANSON JA, DOUTRE WH, FULLER LE. PHYSICIAN PERCEPTION OF A TRIPLICATE PRESCRIPTION LAW. AM J HOSP PHARM. 1985;42:857-859.

(31) WEINTRAUB M, SINGH S, BYRNE L, MAHARAJ K, GUTTMACHER L. CONSEQUENCES OF THE 1989 NEW YORK STATE TRIPLICATE BENZODIAZEPINE PRESCRIPTION REGULATIONS. JAMA. 1991;266:2392-2397.

(32) WASTILA LJ, BISHOP C. THE INFLUENCE OF MULTIPLE COPY PRESCRIPTION PROGRAMS ON ANALGESIC UTILIZATION. J PHARM CARE PAIN SYMPTOM CONTROL. 1996;4(3):3-19.

(33) COOPER JR, CZECHOWICZ DJ, MOLINARI SP, PETERSEN RC. IMPACT OF PRESCRIPTION DRUG DIVERSION CONTROL SYSTEMS ON MEDICAL PRACTICE AND PATIENT CARE. NIDA RESEARCH MONOGRAPH 131. ROCKVILLE, MD: NATIONAL INSTITUTE ON DRUG ABUSE, 1993.

(34) INDIANA BOARD OF PHARMACY. REPORT OF THE INDIANA BOARD OF PHARMACY TO THE LEGISLATIVE COUNCIL CONCERNING THE ELECTRONIC MONITORING OF CONTROLLED SUBSTANCES. INDIANAPOLIS, IN: INDIANA BOARD OF PHARMACY, 1997.

(35) MICHIGAN DEPARTMENT OF COMMERCE, MICHIGAN CONTROLLED SUBSTANCES ADVISORY COMMISSION. MICHIGAN TRIPLICATE PRESCRIPTION PROGRAM: EVALUATION REPORT. EAST LANSING, MI: MICHIGAN DEPARTMENT OF COMMERCE, 1993.

(36) MICHIGAN DEPARTMENT OF CONSUMER & INDUSTRY SERVICES, MICHIGAN CONTROLLED SUBSTANCES ADVISORY COMMISSION. MICHIGAN OFFICIAL PRESCRIPTION PROGRAM: EVALUATION REPORT. EAST LANSING, MI: MICHIGAN DEPARTMENT OF CONSUMER & INDUSTRY SERVICES, 1997.

(37) NEW YORK STATE DEPARTMENT OF HEALTH. BENZODIAZEPINES: ADDITIONAL EFFECTS OF THE TRIPLICATE PROGRAM. N Y STATE J MED. 1990;90:273-275.

(38) NEW YORK STATE DEPARTMENT OF HEALTH. BENZODIAZEPINES: PRESCRIBING

DECLINES UNDER TRIPLICATE PROGRAM. N Y STATE J MED. 1990;90:218-220.

(39) INSTITUTE OF MEDICINE COMMITTEE ON OPPORTUNITIES IN DRUG ABUSE RESEARCH. PATHWAYS OF ADDICTION: OPPORTUNITIES IN DRUG ABUSE RESEARCH. WASHINGTON, D.C.: NATIONAL ACADEMY PRESS, 1996.

(40) FEDERATION OF STATE MEDICAL BOARDS OF THE UNITED STATES INC. MODEL GUIDELINES FOR THE USE OF CONTROLLED SUBSTANCES FOR THE TREATMENT OF PAIN. EULESS, TEX: FEDERATION OF STATE MEDICAL BOARDS OF THE UNITED STATES INC, 1998. (CAN BE ACCESSED UNDER "POLICY DOCUMENTS" AT HTTP://WWW.FSMB.ORG)

(41) DRUG ENFORCEMENT ADMINISTRATION. PHARMACIST'S MANUAL: AN INFORMATIONAL OUTLINE OF THE CONTROLLED SUBSTANCES ACT OF 1970. WASHINGTON, D.C.: U.S. DEPARTMENT OF JUSTICE, 2001. (CAN BE ACCESSED AT HTTP://WWW.DEADIVERSION.USDOJ.GOV/PUBS/MANUALS/PHARM2/INDEX.HTM).

(42) DRUG ENFORCEMENT ADMINISTRATION. MID-LEVEL PRACTITIONER'S MANUAL: AN INFORMATIONAL OUTLINE OF THE CONTROLLED SUBSTANCES ACT OF 1970. WASHINGTON, D.C.: U.S. DEPARTMENT OF JUSTICE, 1993.

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Original Article

Controlled Substances and Pain Management: Changes in Knowledge and Attitudes of State Medical Regulators

Aaron M. Gilson, PhD and David E. Joranson, MSSW
Pain & Policy Studies Group, Comprehensive Cancer Center, University of Wisconsin, Madison, Wisconsin, USA

Abstract
Physicians report that concern about regulatory investigation negatively influences their prescribing of opioid analgesics. The views of medical regulators about the legality of prescribing controlled substances for pain management were studied in 1991. However, little is known about whether these views have changed in light of increased emphasis on pain management and educational programs for state medical boards. Two studies that examined this issue are described. In Study 1, a 1997 survey of state medical board members was compared to results obtained in 1991 to evaluate differences in knowledge and perceptions about opioid analgesics. Important changes were observed over time, particularly regarding characteristics of "addiction" and the legality of prolonged prescribing of opioids. For Study 2, a longitudinal survey was conducted of medical board members who participated in five workshops about pain management and regulatory policy. Results revealed significant and sustained changes in attitudes about the incidence of iatrogenic addiction when using opioids to treat pain, the analgesic and side-effect properties of opioids, and the perceived legality of prescribing opioids. Recommendations for reducing concerns about regulatory scrutiny are presented, including the need for a more intensive education program, increasing the rate of adoption of new state medical board policies, and improving communication between regulators and clinicians. J Pain Symptom Manage 2001;21:227–237. *© U.S. Cancer Pain Relief Committee, 2001.*

Key words
Medical boards, pain policy, chronic pain, cancer pain, opioids

Introduction

In the U.S., inadequate relief of pain is prevalent.[1–3] Although there are many effective pharmacological and non-pharmacologic pain treatments available, opioids are essential for the medical management of moderate to severe acute pain[4] and pain due to cancer.[1,5,6] There is also a consensus of pain medicine and regulatory experts that opioids are appropriate for selected patients with chronic noncancer pain.[7–10]

Opioids are controlled substances and are subject to additional prescription requirements.[11] Their status as controlled substances, however, is not intended to affect their legitimate medical use.[12] Prescribing opioid analgesics for pain is a legitimate medical practice if done in the course of professional practice, and has been

Address reprint requests to: Aaron M. Gilson, PhD, Pain & Policy Studies Group, University of Wisconsin—Madison, 1900 University Avenue, Madison, WI 53705 USA.

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recognized as such by regulatory and legislative groups.[13–17] Prescribing opioids for pain patients with a history of, or current, substance abuse also is a legitimate medical practice, as long as its purpose is for pain, and not to treat addiction. The use of opioids (narcotic drugs) for the treatment of addiction is not a legitimate medical practice unless the practitioner is registered as a Narcotic Treatment Program to dispense (but not prescribe) approved drugs such as methadone according to strict federal and state regulations.[18] The long history of the regulation of opioids as controlled substances, the further regulation of their use for the treatment of "narcotic addiction," and misunderstanding of addiction has contributed to confusion regarding the legality of prescribing under various circumstances.[19,20]

Physicians' concerns about being investigated by controlled substances agencies or state medical boards for prescribing "excessive" amounts or for the wrong patients can negatively affect prescribing practices.[11,21–27] Although there is little evidence to support a high risk of regulatory sanction for prescribing opioid analgesics legitimately for pain,[24,28] physician fears of disciplinary action and criminal prosecution are heightened by national media coverage of a small number of investigations of doctors who have been charged with prescribing opioids excessively.[29–31] Concern about prescribing opioids exists not only among physicians in general practice, but also among oncologists[32] and pain specialists.[33]

A study in 1991 examined the question of whether physicians are justified in their concern about regulatory oversight.[34] A survey was used to evaluate state medical board members' knowledge and attitudes about the medical use of opioids for chronic cancer and noncancer pain. The results showed that medical board members often defined "addiction" to include "physical dependence" or "tolerance," which are common in chronic pain patients treated with opioids. Neither physical dependence nor tolerance is sufficient to define addiction.[1,5,7] In fact, in 1969 the World Health Organization replaced the term "addiction" with "drug dependence," which, like addiction, is characterized primarily by compulsive use of a drug despite harm to the individual.[35] Confusion of physical dependence or tolerance with addiction raises the possibility that a physician's opioid for a chronic pain patient could be viewed as questionable medical practice, if not illegal. Indeed, the 1991 survey showed that many board members did not accept extended prescribing of opioid analgesics to treat chronic pain, especially chronic noncancer pain; many would discourage or even investigate this practice as a violation of law. If the pain patient had a history of substance abuse, nearly all medical board members would discourage or investigate the prescribing of opioids even though such prescribing—if for pain—would be legal. These results suggested there could indeed be a risk of regulatory investigation or discipline to physicians who prescribe opioids even when for the legitimate medical purpose of treating pain.

Results of the survey of board members were presented to the Federation of State Medical Boards of the U.S. (FSMB). Discussions led to the development of a series of educational workshops about the use of controlled substances for pain management, entitled "Pain Management in a Regulated Environment." Eleven workshops were held between 1994 and 1998 and were designed in cooperation with the FSMB. Faculty members for the workshops represented the American Pain Society, the American Academy of Pain Medicine, the American Society of Addiction Medicine, and the University of Wisconsin Pain & Policy Studies Group (PPSG). The workshop curriculum addressed opioid pharmacology, pain management, and addiction, as well as trends and issues in federal and state policies relating to the use of controlled substances for pain. Both the curriculum and faculty were substantially the same for all 11 workshops. The format of the workshop also allowed discussion of regulatory and clinical practice topics of interest to the participants. Overall, 25% of the total U.S. board member population participated in the workshops, representing 40 state medical boards.[19]

Between 1994 and 1998 there was a substantial increase in the number of pain policies adopted by state medical boards. Some of these policies encouraged better treatment of pain for patients with chronic cancer and noncancer pain, and addressed physicians' concerns about regulatory scrutiny.[36] During this period, there also were national consensus statements about the use of opioids in chronic pain,[1,9] state pain study commissions and task

forces,[37] as well as new intractable pain treatment statutes and regulations.[38] The full text for the consensus statements and policies that relate to the treatment of chronic pain can be found on the PPSG website: www.medsch.wisc.edu/painpolicy.

In light of this educational and policy activity, two studies were designed to determine whether the views of state medical regulators about the long-term use of opioid analgesics had changed. In Study 1, we re-surveyed all state medical board members in 1997 to evaluate any changes in knowledge and attitudes since 1991. In Study 2, we evaluated whether changes occurred in a different group of medical board members who participated in any of the five educational workshops about pain management that were held in 1998. Pre-test, post-test, and follow-up surveys were given to all participants to assess changes in their knowledge and attitudes about opioid analgesics and the legitimacy of prescribing such drugs for pain.

Study 1: Re-Survey of State Medical Board Members

Two specific aims guided analyses of the 1997 re-survey of medical board members. First, responses from the 1997 sample of medical board members were compared to those from the 1991 sample. Second, respondents from the 1997 sample who had participated in any of the six pain management workshops held between 1994 and 1996 were compared to those who had not participated. The purpose of this analysis was to determine any changes in knowledge and attitudes that might be due to participation in the workshops.

Methods

Instruments

The 1997 study used a self-report questionnaire consisting of 34 pre-tested items about clinical and policy issues related to pain. The items included those from the 1991 survey,[34] as well as six items to evaluate new topics of interest. The results presented in this article address respondents' perceptions in four major areas: (1) cancer pain and its treatment; (2) nature and extent of opioid analgesic addiction, abuse, and diversion; (3) medical board policies and legal impediments to pain management; and (4) legality of prolonged opioid prescribing in several different patient scenarios.

Sample

The revised "Pain Management Survey" was mailed to a complete list of 700 state medical board members (excluding board administrators and executives) provided by the FSMB. A cover letter stating the purpose of the study and assuring confidentiality of the individual responses accompanied each survey. Two additional mailings were sent to non-responders. Data collection for this study occurred between March–July 1997.

A total of 376 questionnaires (54%) were returned, of which 368 were evaluable for an overall response rate of 53%. Respondents represented all 50 states, as well as the District of Columbia and Puerto Rico, with a mean of seven respondents per state.

Statistical Analysis

The variables of interest for this study had statistically non-normal distributions, which led to the use of non-parametric methods for independent samples to analyze the data. Survey items were analyzed to determine their association with the following two dichotomous groups: (1) respondents from either the 1991 or 1997 sample, and (2) respondents who did or did not participate in a pain management workshop. The Mann-Whitney (MW) test was used to compare the groups for variables that were either ordinal or categorical. The chi-square test of association was used to compare groups with respect to nominal variables. A 0.05 level of significance was used for all statistical tests.

Results for Specific Aim I: Comparison of Respondents from the 1991 and 1997 Surveys

Sample

Due to the national turn-over rate of board members, only 6% of the 1997 respondents (n = 20) had participated in the 1991 survey. The results presented here, therefore, reflect differences in the knowledge and perceptions of two separate groups of board members.

Demographic characteristics of the 1997 board

members, as well as for those surveyed in 1991, are shown in Table 1. The two samples are quite similar. Mean age of the respondents in 1997 was 56 years (range, 34–81 years). Length of service on a state board ranged from 1 to 25 years and represented a mean of 5 years. The vast majority of board members were physicians. Sixteen percent of the respondents were public members and 4% were other health professionals. Thirteen percent of the sample were members of a state osteopathic board. Physician respondents received their medical degrees between 1943 and 1991; their median year of graduation was 1966. This was the only demographic variable that was statistically significant between the 1991 and 1997 samples (MW[535] = −5.276, $P < .0001$), and is merely a reflection of the six-year difference between survey time-frames.

Cancer Pain and Its Treatment

Board members surveyed in the 1997 sample were more likely than those in 1991 to understand the extent to which cancer pain relief is possible. Board members in 1997 believed that significantly more cancer-related pain could be relieved using available therapies, including opioid analgesics (MW[650] = −3.396, $P < .001$). More respondents in 1997 viewed the majority of cancer pain patients in their state as "undermedicated" ($\chi^2[2] = 11.146$, $P < .005$). Thus, medical regulators were more likely in 1997 than in 1991 to recognize that opioids are underutilized as analgesics for cancer pain.

Addiction, Abuse, and Diversion

There were no differences in board members' responses between 1997 and 1991 regarding the perceived approximate incidence of psychological dependence ("addiction") or about the extent that diversion and abuse of prescription opioids was a problem in their community. Most respondents in both surveys overestimated the incidence of addiction and considered diversion to be a minor to moderate problem. The only statistically significant difference between samples involved board members' knowledge about the meaning of "addiction." Board members were asked to define addiction using a brief list of several common terms, such as "physical dependence," "psychological dependence," "tolerance," or a

Table 1
Demographic Characteristics of Survey Respondents

Characteristics	Year of Survey			
Full sample	No. of 1991 surveys ($n = 304$)	%	No. of 1997 surveys ($n = 368$)	%
Age (years)				
Mean	55.22		55.67	
SD	10.93		10.62	
Board type				
Medical	269	88.5	322	86.8
Osteopathic	35	11.5	46	13.2
Status of board member				
Current member	300	98.7	360	97.8
Past member	4	1.3	8	2.2
Capacity of board member				
Physician member	241	79.3	284	77.2
Public member	46	15.1	57	15.5
Other health professional member	10	3.3	16	4.3
"Other" member	7	2.3	6	1.6
Missing	0	0	5	1.4
Time served on board (years)				
Mean	4.51		4.54	
SD	4.01		3.68	
Physician members only				
Year of medical degree, Median	1961		1966	
Currently practicing medicine				
Yes	229	93.5	260	89.3
No	16	6.5	31	10.7

combination of terms. In 1997, fewer respondents associated addiction solely with physical dependence ($\chi^2[1] = 9.558$, $P < .005$). Conversely, there was a much greater likelihood in 1997 for board members to define addiction as psychological dependence alone ($\chi^2[1] = 28.669$, $P < .001$).

Policy Awareness

Respondents surveyed in 1997 reported more often that their state medical board has a policy or guideline for the appropriate prescribing of opioid analgesics for pain management ($\chi^2[1] = 25.003$, $P < .001$). This result reflects the increase in the number of pain policies that were adopted by state medical boards between 1991 and 1997.[36]

Legality of Prescribing Opioids

Board members were asked to judge the legality of prescribing opioids for more than several months in four different patient scenarios: (1) chronic cancer pain, (2) chronic cancer pain with a history of opioid abuse, (3) chronic noncancer pain, and (4) chronic noncancer pain with a history of opioid abuse. The response options were that the practice was: (1) Lawful and generally acceptable medical practice, (2) Lawful but generally not acceptable and should be discouraged, (3) Probably a violation of state medical practice laws or regulations and should be investigated, (4) Probably a violation of federal or state controlled substances laws and should be investigated, and (5) Don't know. More than one response could be chosen by individuals who believed that both categories of illegality were applicable. Table 2 contains the frequencies of responses within each chronic pain scenario for 1991 and 1997.

Cancer pain scenarios. Compared to respondents in 1991, those in 1997 viewed the prescribing of opioids for more than several months for cancer pain as both lawful and acceptable medical practice ($\chi^2[4] = 18.598$, $P < .001$). Likewise, when the cancer patient also had a history of opioid abuse, medical board members surveyed in 1997 were more likely than those in 1991 to view opioid prescribing as lawful and generally acceptable ($\chi^2[4] = 18.123$, $p < .001$).

Noncancer pain scenarios. Compared to the two cancer-related scenarios, medical board members were generally much more skeptical about prescribing opioids for noncancer pain. Respondents in 1997 were more likely than in 1991 to consider prescribing to patients with chronic noncancer pain for more than several months as acceptable medical practice ($\chi^2[4] = 62.200$, $p < .001$). These regulators viewed the

Table 2
Legality and Medical Acceptability of Extended Opioid Prescribing, 1991 Compared to 1997

	Level of Perceived Legality									
	Lawful and generally acceptable medical practice; no need to investigate		Lawful and generally not acceptable medical practice; should be discouraged		Violation of medical practice laws and regulations; should be investigated		Violation of controlled substances laws; should be investigated		Don't know	
Year	1991	1997	1991	1997	1991	1997	1991	1997	1991	1997
Cancer pain	75%	82%	14%	5%	5%	2%	5%	2%	7%	5%
Cancer pain with history of opioid abuse	46%	57%	22%	17%	14%	6%	12%	4%	16%	11%
Chronic noncancer pain	12%	33%	47%	40%	32%	11%	27%	6%	7%	6%
Chronic noncancer pain with history of opioid abuse	1%	6%	25%	36%	58%	34%	50%	20%	6%	6%

Note: Rows do not sum to 100% because respondents could give more than one response.

prolonged prescribing of opioids to a patient with chronic noncancer pain and a history of drug abuse as least acceptable. However, medical board members in 1997 were more likely to view such prescribing as a lawful and acceptable medical practice ($\chi^2[4] = 37.630$, $p < .001$). Although statistically significant, it should be noted that only 6% of the 1997 sample gave this response.

Results for Specific Aim II: Analysis of Workshop Participants

Twelve percent ($n = 41$) of the 1997 board members reported that they had participated in one of the six workshops on pain management held between 1994 and 1996. This subsample was large enough to compare the responses of participants and non-participants on a limited set of survey items. To preserve the statistical power of the analyses, only those items were analyzed that relate to the legality of prescribing opioids for pain.

There were no statistically significant differences in responses to the cancer pain scenarios. Indeed, a majority of board members, whether or not they had participated in a workshop, were confident in the legal and medical acceptability of this practice. Board members who attended workshops were moderately more likely than those who did not attend to view prescribing opioids for noncancer pain as lawful and generally accepted medical practice, although this finding did not achieve statistical significance. However, workshop participants were much more likely to consider the prescribing scenario involving noncancer pain and a history of opioid abuse as an acceptable medical practice ($\chi^2[2] = 11.503$, $P < .005$). Since there is generally a greater reluctance to view prescribing for patients with noncancer pain or a history of drug abuse as legitimate, it is encouraging that participation in the education program was associated with increased acceptance of this practice.

Study 2: Prospective Survey of Workshop Participants

Study 2 was a longitudinal assessment of changes in knowledge and attitudes among medical board regulators who participated in any of the five workshops held in 1998.

Methods

Instruments

The evaluation was conducted using a 31-item self-report questionnaire. Most of the items addressed the workshop content and a few were adapted from the 1991 and 1997 surveys of medical board members.[34] The survey addressed: (1) cancer pain and its treatment, (2) addiction issues, (3) analgesic efficacy and side-effects of opioids, and (4) perceived legality of prolonged prescribing of opioids in several different patient scenarios. Each participant completed the survey three times: Before the workshop (pre-test), immediately after its completion (post-test), and after approximately six months (follow-up).

Sample

The sample for this study was all participants in five regional medical board workshops co-sponsored by the PPSG and the FSMB in 1998. Curriculum and the faculty was similar for each workshop, and addressed the nature and extent of pain, the barriers to adequate relief, both pharmacologic and non-pharmacologic treatments for pain, the appropriate medical use of opioids, definition and prevalence of addiction, and the current status of pain management and controlled substances policies.

Statistical Analysis

All data were analyzed using non-parametric methods at a 0.05 significance level. Chi-square tests were used to evaluate whether workshop participation was significantly associated with the categorical survey items. The effect of the time of assessment (i.e., pre-test, post-test, and follow-up) on any continuous dependent variable was calculated using the Wilcoxon matched-pair signed-rank test. This method of statistical analysis typically identifies changes that are significant using the pre-test as the point for comparison.

Results

Sample

Seventy workshop participants were surveyed at pre-test. Age of the participants ranged from 28 to 83 years, with a mean age of 54 years (SD = 10.32). Males represented slightly more than half (57%) of the sample. The workshop audience

consisted of physician members (49%), investigators (10%), executive directors or secretaries (9%), attorneys (9%), public members (7%), and "other" board members (16%). Length of service on the board ranged from 1 to 21 years, with a mean of 5 years. Physician members reported that they had received their medical degrees between 1952 and 1984, with a median of 1964. A large majority of physician respondents (87%) were currently practicing medicine.

As expected with any longitudinal study design, sample attrition occurred at follow-up assessment, decreasing 36% from pre-test to follow-up, with 45 respondents submitting a completed survey after six months. Loss of participants can lead to sample bias if the final sample varies considerably from the initial group of respondents. Demographic characteristics of the pre-test and follow-up samples were, therefore, compared to determine the extent of dissimilarity. If sample differences are found at the time of the follow-up survey, changes in responses across time can result from such differences rather than from workshop participation. There were no statistically significant differences between the pre-test and follow-up samples on any demographic characteristic.

Cancer Pain and Its Treatment

Workshop participants were more likely both at post-test (Wilcoxon[61] = 2.895, $P < .005$) and follow-up (Wilcoxon[36] = 3.737, $P < .001$) to believe that available therapies, including opioid analgesics, can relieve cancer pain effectively. In addition, board members were less familiar at pre-test about the degree to which patients under-report pain ($\chi^2[8] = 17.461$, $P < .05$). (A significant chi-square result indicated variability in responses given by the same individual at pre-test, post-test, and follow-up. Adjusted standardized residuals were then used to identify the patterns in the data that contributed to the statistical significance. In all instances of statistical significance, the largest residual was found at pre-test (i.e, pre-test was the reference category). As a result, significant chi-square associations are interpreted in terms of different responses being given at pre-test, as compared to post-test and follow-up.) It appears that the workshops increased participant awareness of the potential for patients to under-report pain.

Addiction

At pre-test, medical regulators viewed addiction as a frequent occurrence when opioids are used for a prolonged period of time ($\chi^2[8] = 31.548$, $P < .001$), and defined addiction as physical dependence ($\chi^2[8] = 29.144$, $P < .001$). Since these beliefs were significantly less prevalent after participating in the workshop, the survey results suggest that the workshop was successful in clarifying the definition of addiction.

Analgesic and Side Effect Properties of Opioids

Medical regulators were less likely to understand the pharmacodynamics of opioid analgesics prior to the workshop. Respondents were less likely to know at pre-test whether prolonged opioid use leads to a deterioration of organ functioning ($\chi^2[6] = 29.493$, $P < .001$) or to a decrease in cognitive function ($\chi^2[8] = 26.612$, $P < .001$). Before the workshop, participants also were more likely to believe that there is a ceiling to the analgesic effect of morphine ($\chi^2[8] = 51.309$, $P < .001$), and that tolerance diminished the analgesic efficacy of opioids ($\chi^2[8] = 42.673$, $P < .001$). In general, there was a greater likelihood of inaccurate knowledge about the effects of opioids prior to the workshop.

Legality of Prolonged Opioid Prescription

The same four patient scenarios were used from the national survey of medical board members. Four response options were provided: (1) Lawful and generally acceptable medical practice, (2) Lawful but generally not acceptable and should be investigated, (3) Probably a violation of federal or state controlled substances or medical practice laws and should be investigated, and (4) Don't know. Only one response could be chosen for each patient scenario. Table 3 contains the frequencies of responses within each chronic pain scenario for the pre-test, post-test, and follow-up.

Cancer pain scenarios. Compared to responses given at both post-test and follow-up, respondents at pre-test were less likely to view the prolonged prescribing of opioids for cancer pain as a lawful and accepted medical practice ($\chi^2[6] = 18.701$, $P < .005$). Likewise, when the cancer patient also had a history of opioid abuse, a lower proportion of regulators surveyed at pre-test viewed the prescribing of opi-

Table 3
Legality and Medical Acceptability of Extended Opioid Prescribing at Pre-test, Post-test and Follow-up

	Level of Perceived Legality											
	Lawful and generally accepted medical practice			Lawful but generally not accepted medical practice; should be investigated			Violation of federal and state laws; should be investigated			Don't know		
Assessment Period	1	2	3	1	2	3	1	2	3	1	2	3
Cancer pain	77%	98%	95%	6%	0%	0%	3%	0%	2%	14%	2%	2%
Cancer pain w/Hx of substance abuse	54%	76%	68%	16%	16%	25%	9%	2%	3%	22%	7%	5%
Chronic noncancer pain	38%	75%	60%	33%	22%	30%	10%	0%	5%	19%	3%	5%
Chronic noncancer pain w/Hx of substance abuse	17%	48%	36%	44%	37%	49%	17%	10%	10%	21%	6%	5%

Note: Assessment Period 1 = pre-test results.
Assessment Period 2 = post-test results.
Assessment Period 3 = follow-up results.
Note: Rows may not add up to 100% due to rounding error.

oids as lawful and generally accepted ($\chi^2[6] = 16.732, P < .01$).

Noncancer pain scenarios. The findings for both the noncancer pain scenarios were similar to those obtained for the two cancer pain scenarios. Prior to workshop participation, respondents were less likely to consider as legal and acceptable medical practice the long-term prescribing of opioids to patients with chronic pain not due to cancer ($\chi^2[6] = 25.467, P < .001$), as well as chronic noncancer pain with a history of substance abuse ($\chi^2[6] = 20.577, P < .005$).

Discussion

The second survey of state medical board members (Study 1) revealed that there had been important, although not profound, improvements in knowledge, attitudes, and beliefs since 1991. In 1997, board members were more likely to recognize the efficacy of opioid analgesics for cancer pain, but that cancer pain patients are not adequately treated for pain. In addition, board members in 1997 had greater confidence in all four scenarios that prescribing opioids for chronic pain was legal and accepted medical practice. Although still representing a small percentage of the total sample, more board members in 1997 viewed prescribing of opioids to be lawful and medically acceptable for the treatment of chronic noncancer pain, as well as for those with chronic pain and a history of opioid abuse. This difference between the two samples represents encouraging movement toward recognizing the legitimacy of prescribing that, by today's standards, would be considered acceptable medical practice.[10]

The data also suggest a positive shift in medical board members' understanding of what addiction is and what it is not. Fewer participants in 1997 defined it solely on the basis of the manifestation of a withdrawal syndrome. This represents encouraging movement toward the use of behavioral, rather than physiological, measures of addiction. Nevertheless, physiological interpretations of addiction remain common. A much more concerted effort is needed to bring regulators' understanding of the determinants of addiction up-to-date, as well as be able to determine what constitutes accepted prescribing practices.

The educational workshops described in this article had a lasting impact on medical regulators' understanding of a number of topics. First, there were significant and durable changes in respondents' views about the legality of prescribing for chronic pain for a prolonged pe-

riod. Fewer regulators at pre-test viewed prescribing opioids for more than several months as legal and acceptable medical practice in the four patient scenarios. Second, regulators had modified their definitions of addiction. Before the workshop, participants were much more likely than at post-test or at six-month follow-up to characterize addiction as physical dependence only. Following the workshop, they were more likely to recognize that addiction is a behavioral syndrome characterized by compulsive craving of a drug for its psychological effects and continued use despite harm. Third, regulators were more likely after the workshop to estimate the low incidence of addiction correctly when opioid analgesics are used to treat chronic pain in patients who do not have prior substance abuse histories. Finally, the workshop increased these board members' understanding that the low potential for substantial physiological or cognitive impairments should not contraindicate the long-term use of opioids.

These studies show that there has been a relatively small but positive change in state medical board members' knowledge and attitudes about the use of opioid analgesics to treat both cancer and noncancer pain. These changes are taking place at the same time that pain relief is becoming more visible and that boards are issuing new pain management policies, some of which recognize that prescribing opioids for chronic noncancer ;pain is considered legitimate medical practice and that physicians should not fear regulatory discipline for such prescriptions. Although statistically significant changes in knowledge and attitudes were observed over time and as a result of involvement in an educational workshop, most medical board members continued to view prolonged prescribing of opioid analgesics for chronic noncancer pain as inappropriate medical practice and something to be discouraged or even investigated. In addition, there continues to be confusion about the characteristics of addiction and about the approximate incidence of iatrogenic addiction. If there is confusion among regulators about addiction, then there is the potential to investigate physicians for prescribing practices that may conform to present standards.

Improving pain management in the U.S. will depend, in part, on a three-part program that includes: (1) more intensive educational programs for state medical board members and staff, (2) accelerated policy development by state medical boards to encourage pain management and address concerns about regulatory scrutiny, and (3) increased communication between clinicians and their regulators.

1. Education. State medical boards should sponsor educational efforts for their members, staff, investigators, and attorneys to update their knowledge and views about pain management and regulatory policy. An excellent example is provided by the medical boards in Alabama and North Carolina; they held educational workshops to inform their members and staff.[38] After the workshops, these boards adopted guidelines to recognize the use of controlled substances for the treatment of chronic pain.[17,39]
2. Policy. State medical boards should adopt or amend their existing guidelines according to the national standard established by the FSMB's "Model Guidelines for the Use of Controlled Substances for the Treatment of Pain."[10] (It is recognized that many state medical boards have already adopted guidelines; however, some of these policies fail to encourage pain management or address directly licensees' concerns about regulatory scrutiny.) The Model Guidelines offer significant advantages over current state medical board policies.[17,19] The Model Guidelines address physician concern about investigation or discipline directly, so that:

> Physicians should not fear disciplinary action from the Board or other state regulatory or enforcement agency for prescribing, dispensing, or administering controlled substances, including opioid analgesics, for a legitimate medical purpose and in the usual course of professional practice. (p. 2)[10]

Indeed, the Model Guidelines are an unprecedented consensus among groups that represent pain management, regulatory, and drug law enforcement about the medical use of controlled substances for the treatment of pain.[17]

3. Communication. Once a state medical board has updated its views about pain management and has adopted or adapted

the Model Guidelines, they should disseminate and publicize the policy widely and repeatedly to encourage positive practice change and reduce concerns about regulatory scrutiny.[10,17,21] (It is recognized that state policies may differ and that boards may adapt and improve on the Model Guidelines.) Despite initial dissemination efforts by medical boards, practitioners may be unaware of the board's policy.[17,40] The North Carolina Medical Board (NCMB) provides an example of what state boards can do: In addition to systematic dissemination of its guidelines, the NCMB sponsored educational programs and media events for health-care professionals and for the public.[39]

We should not be surprised that knowledge and attitudes are slow to change. However, these studies show that change is indeed occurring. We can accelerate the rate of change with more concentrated efforts. Increasingly, state medical boards and their members and staff are coming to recognize that pain control is a significant health-care problem, and that they have an important role to play in eliminating fears of regulatory scrutiny. Making this a reality will require additional efforts and further cooperation between medical boards and the pain management community.

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References

1. Jacox A, Carr DB, Payne R, et al. Management of cancer pain. Clinical Practice Guideline. No. 9. AHCPR Publication No. 94-0592. Rockville, MD: Agency for Health Care Policy and Research, Public Health Service, U.S. Department of Health and Human Services, March 1994.

2. Institute of Medicine. Approaching death: improving care at the end of life. Washington, DC: National Academy Press, 1997.

3. SUPPORT Study Principle Investigators. A controlled trial to improve care for seriously ill hospitalized patients: the study to understand prognoses and preferences for outcomes and risks of treatments (SUPPORT). JAMA 1995;274:1591–1598.

4. Acute Pain Management Guideline Panel. Acute pain management: operative or medical procedures and trauma. Clinical Practice Guideline. AHCPR Pub. No. 92-0032. Rockville, MD: Agency for Health Care Policy and Research, Public Health Service, U.S. Department of Health and Human Services, February 1992.

5. World Health Organization. Cancer pain relief with a guide to opioid availability. Geneva, Switzerland: WHO, 1996.

6. World Health Organization. The use of essential drugs: report of a WHO Expert Committee (Technical Report Series 882). Geneva, Switzerland: WHO, 1998.

7. Savage SR. Opioid use in the management of chronic pain. Med Clin North Am 1999;83:761–786.

8. Portenoy RK. Opioid therapy for chronic nonmalignant pain: clinicians' perspective. J Law, Med & Ethics 1996;24:296–309.

9. American Academy of Pain Medicine and American Pain Society. The use of opioids for the treatment of chronic pain: A consensus statement. American Academy of Pain Medicine and American Pain Society, 1997.

10. Federation of State Medical Boards of the United States, Inc. Model guidelines for the use of controlled substances for the treatment of pain. Euless, TX: FSMB, May 1998.

11. Joranson DE, Gilson AM. Controlled substances, medical practice, and the law. In: Schwartz HI, ed. Psychiatric practice under fire: the influence of government, the media, and special interests on somatic therapies. Washington, DC: American Psychiatric Press, 1994:173–194.

12. Controlled Substances Act of 1970. Pub L No 91-513, 84 Stat 1242.

13. *Code of Federal Regulations. Title 21 Part 1306.* 04-1306.12.

14. Drug Enforcement Administration. Physician's manual: an informational outline of the Controlled Substances Act of 1970. Washington, DC: U.S. Department of Justice, March 1990.

15. National Conference of Commissioners on Uniform State Laws. Uniform Controlled Substances Act. Chicago, IL: NCCUSL, July 29–August 5, 1994.

16. Joranson DE, Gilson AM. Regulatory barriers to pain management. Sem Nurs Oncol 1998;14:158–163.

17. *Joranson DE, Gilson AM. Controlled substances* and pain management: a new focus for state medical boards. Fed Bull 1998;85:78–83.

18. Joranson DE. Is methadone maintenance the last resort for some chronic pain patients? Amer Pain Soc Bull 1997;7:1, 4–5.

19. Joranson DE, Gilson AM, Dahl JL, Haddox JD. State medical boards, controlled substances, and

pain management: a decade of change. JAMA (under review).

20. Weissman DE. Doctors, opioids, and the law: the effect of controlled substances regulations on cancer pain management. Sem Oncol 1993;20:53–57.

21. Haddox JD, Aronoff GM. Commentary: the potential for unintended consequences from public policy shifts in the treatment of pain. J Law, Med & Ethics 1998;26:350–352.

22. Hill CS Jr. The negative effect of regulatory agencies on adequate pain control. Prim Care Cancer 1989;November:45–53.

23. Hill CS Jr. The barriers to adequate pain management with opioid analgesics. Sem Oncol 1993; 20(2 Suppl 1):1–5.

24. Martino AM. In search of a new ethic for treating patients with chronic pain: what can medical boards do? J Law, Med & Ethics 1998;26:332–334.

25. Weissman DE, Joranson DE, Hopwood MB. Wisconsin physicians' knowledge and attitudes about opioid analgesic regulations. Wisc Med J 1991;December:53–58.

26. Turk DC, Brody MC, Okifuji EA. Physicians' attitudes and practices regarding the long-term prescribing of opioids for noncancer pain. Pain 1994; 59:201–208.

27. Portenoy RK. Opioid therapy for chronic nonmalignant pain: current status. In: Fields HL, Liebeskind JC, eds. Progress in pain research and management, Volume 1. Seattle, WA: IASP Press, 1994:247–287.

28. Johnson SH. Disciplinary actions and pain relief: analysis of the Pain Relief Act. J Law, Med & Ethics 1996;24:319–327.

29. McIntosh H. Regulatory barriers take some blame for pain undertreatment. J Nat Cancer Inst. 1991;83:1202–1204.

30. In the Matter of DiLeo. 661 So. 2d 162 (La. Appl. 1995).

31. Hoover v. Agency for Health Care Administration. 676 So. 2d 1380 (Fla. Dist. Ct. App. 1996).

32. Von Roenn JH, Cleeland CS, Gonin R, et al. Physician attitudes and practice in cancer pain management: a survey from the Eastern Cooperative Oncology Group. Annals Intern Med 1993;119:121–126.

33. Turk DC, Brody MC. What position do APS's physician members take on chronic opioid therapy? Amer Pain Soc Bull 1992;2:1–5.

34. Joranson DE, Cleeland CS, Weissman DE, Gilson AM. Opioids for chronic cancer and noncancer pain: a survey of state medical board members. Fed Bull 1992;79:15–49.

35. WHO Expert Committee on Drug Dependence. Sixteenth report. (Technical Report Series 407). Geneva, Switzerland: WHO, 1969.

36. Joranson DE, Gilson AM. State intractable pain policy: current status. Amer Pain Soc Bull 1997;7:7–9.

37. Joranson DE. State pain commissions: new vehicles for progress? Amer Pain Soc Bull 1996;6:7–9.

38. Joranson DE. Intractable pain treatment laws and regulations. Amer Pain Soc Bull 1995;5:1–3,15–17.

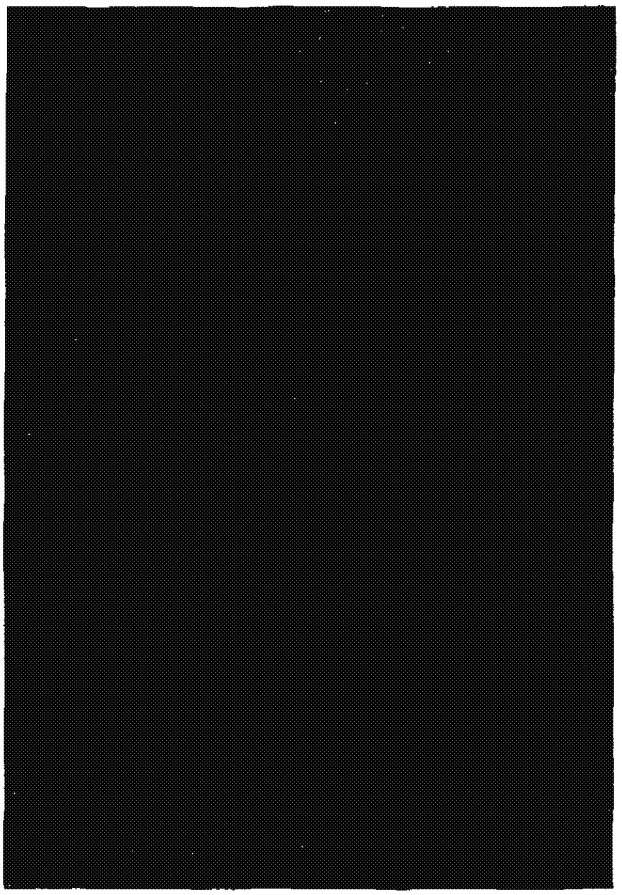
39. Joranson DE, Gilson AM. Improving pain management through policy making and education for medical regulators. J Law, Med & Ethics 1996;24: 344–347.

40. Potter MB, Schafer S, Croughan-Minihane M. Opioids in the treatment of chronic nonmalignant pain: the attitudes and practices of primary care physicians. San Diego, CA: Poster presented at the 17th annual American Pain Society conference, November 1998.

June L. Dahl, PhD
Mary E. Bennett, MFA
Matthew D. Bromley, BS
David E. Joranson, MSSW

Success of the State Pain Initiatives

Moving Pain Management Forward



Despite major medical and scientific advances, the undertreatment of pain remains a major public health problem in this country. The documentation of the inadequacy of cancer pain management began with the pioneering work of Charles Cleeland and his colleagues[1] in the early 1980s and persists to this day.[2–6] It should therefore come as no surprise that respondents to a survey commissioned by *Modern Maturity* magazine in 2000 said that they feared dying in pain more than they feared death itself.[7] The reasons for undertreatment also have been well documented, and they include inadequate knowledge and inappropriate attitudes of healthcare professionals, patient and family fears and misconceptions, barriers in the drug regulatory system, problems within the system of the delivery of care, as well as inadequate reimbursement for drugs and other therapies.[8–10] Over the past 15 years, State Cancer Pain Initiatives (CPIs) have been working to confront these barriers. CPIs are volunteer grassroots interdisciplinary programs involving physicians, nurses, pharmacists, social workers, psychologists, educators, regulators, clergy, and others. These CPIs disseminate accurate pain management information, educate healthcare professionals, raise public and patient awareness of the cancer pain problem and of the benefits of effective pain control, promote clinical and institutional change, and advocate for the removal of regulatory and legislative barriers to effective pain management.[11–13]

The first state CPI was organized in Wisconsin in 1986 as a project of the World Health Organization.[14] The programs and philosophies of the Wisconsin Cancer Pain Initiative (WCPI) stimulated interest by individuals in other states who were similarly concerned about the inadequacy of cancer pain management. The action plan of the WCPI was based on the following:

- The focus should be on cancer pain at all stages of the disease and not limited to pain in the terminally ill.
- The problem of undertreatment is not due to a lack of effective analgesics and other therapies; the problem is that they are not being used appropriately.
- Pain management educational efforts have not changed practice.
- Any program to improve pain management must address the need to change the attitudes and behaviors of healthcare professionals.

June L. Dahl, PhD, Professor of Pharmacology, University of Wisconsin-Madison Medical School, Past President, American Alliance of Cancer Pain Initiatives, Madison, Wisconsin.

Mary E. Bennett, MFA, Outreach Director, American Alliance of Cancer Pain Initiatives, Madison, Wisconsin.

Matthew D. Bromley, BS, Communications Director, American Alliance of Cancer Pain Initiatives, University of Wisconsin-Madison Medical School, Madison, Wisconsin.

David E. Joranson, MSSW, Senior Scientist, Director, Pain and Policy Studies Group, University of Wisconsin Comprehensive Cancer Center, Madison, Wisconsin.

Address for correspondence: June L. Dahl, PhD, Professor of Pharmacology, University of Wisconsin-Madison Medical School, 1300 University Avenue, Room 4715-A, Madison, WI 53706.

Until the 1990s, there were no organized national efforts to improve cancer pain management, and CPIs filled that void. Other important reasons for the formation of state-based programs relate to the enormous size and geographic and demographic diversity of this nation, and to the fact that regulatory policies and programs are developed and healthcare professionals are trained and licensed at the state level. CPIs can design programs to take advantage of their state's unique strengths and challenges. For example, there are significant differences in the state laws and regulations that govern the prescribing and dispensing of controlled substances. Therefore, in some states, the laws and regulations will be strengths, while in others, regulatory barriers need to be confronted.

National meetings for state CPIs have been held annually since 1989. These meetings provide the opportunity to network, to share expertise and resources, and to build valuable collaborative relationships. Perhaps the only national forums of their kind, these meetings focus specifically on the organizational, educational, ethical, cultural, and policy challenges surrounding the treatment of cancer pain.

In 1996, the leaders of the 44 established CPIs supported the creation of the American Alliance of Cancer Pain Initiatives (AACPI) to provide the state organizations with the following: 1) a communications network; 2) resources and consultation for organizational development; 3) programs and resources to improve pain management; and 4) a national identity.[15] The quarterly newsletter of the AACPI keeps members informed of important clinical issues related to pain management and provides a forum for CPIs to share resources. The AACPI maintains a list serve and a web site (www.aacpi.org) that allows CPI members to easily access information on conferences, events, and pain management resources and provides links to state CPI web sites.

State CPIs clearly recognize that to have maximal impact and sustain the movement, they and the AACPI need to form strong partnerships with other organizations that share common goals. While the state CPI movement was evolving in the last decade, other organizations made pain management a priority in their programs, greatly facilitating the work of the CPIs. In 1991, the Oncology Nursing Society published a position paper that guides the education of nurses and presents a core curriculum on pain.[16] Many members of the Oncology Nursing Society pain special interest group are leaders of their state CPIs. An ad hoc committee of the American Society of Clinical Oncology published a curricular guideline for cancer pain management in 1992.[17] Collaborations with the American Pain Society, the University of Wisconsin Pain & Policy Studies Group, the Cancer Information Service, the American Cancer Society (ACS), Community-State Partnerships to Improve End-of-Life Care, Last Acts, the Association of Oncology Social Workers, the American Society of Pain Management Nurses, the American Pain Foundation, state hospice organizations, and the Intercultural Cancer Council have been important to the CPI movement. Clinical practice guidelines developed by a number of professional organizations are of particular importance to the professional education activities of CPIs, because they bring the authority of national experts to the message of CPIs. The release of the *Cancer Pain Guideline* from the Agency for Health Care Policy and Research (now the Agency for Healthcare Research and Quality) in 1994[18] was of particular importance because it provided national validation of the programs of CPIs. Furthermore, the active involvement of the CPIs in the distribution and media coverage of these guidelines was a great stimulus to individual states and to the movement as a whole.

The multiple programs of the Robert Wood Johnson Foundation to improve end-of-life care also have been of great assistance to the CPI movement.[19] Their emphasis on the importance of effective pain management at the end of life and on broad media coverage of the issue has had a great impact on CPI efforts to improve pain management along the continuum of the disease.

Collaboration with the American Cancer Society

The American Cancer Society (ACS) has a long history of collaborative efforts with state CPIs. Indeed, some CPIs are organized within divisions of the ACS and partner with the ACS on projects. The ACS volunteers and leadership staff have long been eager to address the problems of cancer pain and some have played important roles; yet the institutional emphasis of the ACS has been directed at reducing the incidence of and mortality from cancer as well as at providing patient support in areas other than pain management. Fortunately, the ACS now has broadened its goals to include quality of life, with pain management being a key component. The AACPI and the ACS quickly acknowledged the commonality in their goals and objectives, and the multiple opportunities and models for collaboration. In February 2001, through the generous support of the Robert Wood Johnson Foundation, the AACPI convened a meeting with the ACS and CPI representatives to discuss current exemplary models of ACS-AACPI collaboration and to set the stage for future mutually beneficial collaborations between the two organizations. At that meeting, representatives recognized the special synergy between the ACS and the AACPI, and affirmed their commitment to working together to maximize the unique strengths of each organization. Within 3 months of that meeting, the ACS developed a resource book for their divisions, a component of which is the *Division Guide to Collaboration with State Cancer Pain Initiatives*.[20] This comprehensive document provides background information on the magnitude and impact of unrelieved pain in persons with cancer. It also makes specific recommendations on how ACS divisions can collaborate with state CPIs to improve the treatment of cancer pain.

Current Status of the Cancer Pain Initiatives

There are now 46 CPIs in 44 states, with two in both California and Texas. Ten CPIs have expanded the scope of their efforts to include all pain. More than half of CPI participants are nurses, about 13% are pharmacists, 12% are

physicians, and a smaller percentage are social workers, psychologists, healthcare administrators, and others. Some CPIs have a small number of highly dedicated volunteers who serve as state contacts, while others are well-established organizations and networks that function as driving forces for pain management improvement efforts in their states. The term "small, but mighty" often has been used to describe CPIs, because they are rich in expertise and commitment but typically work with limited resources. Many state CPI leaders report that the most valuable asset of their CPI is its "network" of passionate experts. Many CPIs have formal affiliations with the ACS, state hospice organizations, and Community-State Partnerships to Improve End-of-Life Care; and some are affiliated with academic institutions, hospitals, and other state-based healthcare organizations. These organizations provide the CPIs with a number of resources, including office space, phone lines, email, administrative support, program staff, fax lines, and financial support.

CPIs have, in many different ways, contributed significantly to the improvement of pain management in this country. It is not possible to describe all the accomplishments that each CPI has made. Instead, this article chronicles a few of the many successes of the CPI movement and the critical importance of collaboration with those who share the common goal of promoting pain relief nationwide.

Professional Education

In 1989, the WCPI developed the Cancer Pain Role Model Program,[21] and over the next 10 years conducted 31 role model conferences in 24 states that trained teams of healthcare professionals. These programs often provided the stimulus for the formation of a state CPI. Professional education continues to be one of the top three priorities for state CPIs and is the centerpiece of many of the efforts of CPIs. CPIs produce and distribute a variety of educational materials that are designed to improve healthcare professionals' knowledge of pain management, including handbooks, dosage conversion cards, tabletop displays, and slide kits for educational conferences. CPIs frequently sponsor state or regional conferences, workshops, and seminars on pain management issues for healthcare professionals.

The Arizona Cancer Pain Initiative has trained more than 500 healthcare professionals in cancer pain management since its establishment in 1993. Recently, this CPI held a "Train the Trainers" workshop, which was modeled after the AACPI Institutional Change Projects and the City of Hope Pain Resource Nurse training[22] to improve clinical competence in pain management practices. Pain team leaders were recruited from healthcare facilities throughout the state to lead pain management efforts in their respective organizations.

The bimonthly newsletter of the Alaska Pain Network, "Pain News," provides healthcare professionals with diverse insights into pain management issues from a broad range of perspectives. Pharmacists, nurse practitioners, long-term care facility workers, hospital personnel, military hospital personnel, and representatives from native clinics all have contributed to the newsletter. More than 600 Alaskan healthcare professionals received "Pain News" within the last 3 years, and hundreds more receive electronic versions of the informational newsletter.

The Southern California Cancer Pain Initiative (SCCPI) has been a leader in establishing a viable and effective organization, and it has become a role model for other CPIs. Since its establishment in 1993, the SCCPI has sponsored a multitude of educational programs, including an annual conference on cancer pain management, palliative care, or both, and an American Medical Association Education for Physicians on End-of-Life Care (EPEC) program. It also hosts an annual event to recognize pain champions throughout southern California. The SCCPI has revised its pocket card devoted to "Principles of Cancer Pain Management" and is distributing it to healthcare professionals throughout southern California. Future efforts include the convening of representatives of all California medical schools to explore expanded curricula devoted to cancer pain management, increasing medical involvement in SCCPI courses, developing a formal liaison with each medical school, and the strengthening of the relationship of the CPI with the California Medical Association and county medical societies.

The New Jersey Pain Initiative, a project of the ACS, administers a "Best Practices in Pain Management Program" to improve pain management in healthcare facilities across New Jersey. From November 1999 through December 2000, 23 seminars for 1500 healthcare professionals at 31 partnering organizations were completed. Future endeavors include collaborations with long-term care facilities, physicians, and community pharmacists. A statewide conference was organized for participating organizations with the opportunity for continuing education and the sharing of resources.

Practice and Institutional Change

Initiative leaders recognize that professional education alone does not change practice. Therefore, many CPIs are involved in programs to effect positive changes in pain management practices, policies, and procedures within healthcare organizations. With the support of the Robert Wood Johnson Foundation, the AACPI provided grants to six CPIs (Connecticut, Delaware, Michigan, North Carolina, New Mexico, and Virginia) to implement "Institutional Change Projects." These projects are designed to help small healthcare organizations (eg, long-term care facilities, home health agencies, small community-based hospitals, or a combination) to improve pain management practices. They also are designed to strengthen or revitalize CPIs. The programs educate teams from committed organizations on pain assessment and management, self-assessment of the organization, implementation of an individual organizational change plan, and evaluation of selected patient outcomes. It is estimated that each day more than 20,000 patients are cared for by the healthcare organizations that participated in these programs.

Patient and Public Education

Educating patients and the public about the importance of controlling pain effectively is a major focus of the AACPI and CPIs. In early 2001, the AACPI coordinated a national multimedia campaign surrounding the implementation of new pain standards from the Joint Commission on Accreditation of Health Care Organizations.[23,24] The campaign resulted in prominent coverage on the importance of pain management by most of the national news organizations and in approximately 500 daily newspapers nationwide. A local television news component of the campaign placed 250 news stories about pain management in more than100 television markets nationwide. It is estimated that more than 10 million viewers watched these news stories. In addition, CPIs have actively participated in national medical outreach campaigns, such as the Fall 2000 PBS series "On Our Own Terms: Moyers on Dying in America."[25]

Cancer Pain Relief-Utah engaged in a successful public awareness campaign to inform Utah citizens that cancer pain can be relieved. Part of the campaign included a radio public service announcement that imparted to listeners the following three important messages: 1) pain can be relieved; 2) telling your caregivers about your pain is important; and 3) addiction is not something to fear when using pain medications appropriately for cancer pain. The 60-second public service announcements were aired nearly 4000 times on 35 radio stations throughout Utah, including rural areas that were in desperate need of pain management information. Through the Utah Broadcasters Association, Cancer Pain Relief-Utah was able to obtain more than $275,000 worth of air time for an investment of only $8000.

Through a collaborative effort with Cancer Care Connection, the Delaware Cancer Pain Initiative has helped establish a telephone hotline enabling the public to obtain helpful information on controlling pain. The Delaware Cancer Pain Initiative is promoting the hotline as a primary public information number for pain management information.

Several CPIs have participated in the production of patient education videos, brochures, and other resources as a way to dispel fears and misconceptions about pain control that are commonly held by patients and their families. The North Carolina Pain Initiative, together with state health agencies and the ACS, produced a video ("Living Without Cancer Pain: A North Carolina Success Story") to help the public better understand the treatment of cancer pain. To address the bringing of important health information to rural areas, the Virginia Cancer Pain Initiative produced a video entitled, "Managing Cancer Pain: A Rural Perspective."

Regulatory and Legislative Advocacy

There is increasing interest at the federal and state levels in placing additional restrictions on the prescribing and dispensing of controlled substances. It is the position of CPIs that no additional regulations should be promulgated unless there is clear evidence of the need for such programs, of their benefit in reducing prescription drug abuse and diversion, and of their impact on patient access to pain-relieving drugs. The financial costs associated with setting up and maintaining the administrative structure to support additional regulations is also of concern. It is particularly noteworthy that the National Association of State Controlled Substances Authorities[26] formally endorsed the CPI movement, recognizing that the underlying principle of regulation is to ensure that patients receive the care that they need. Regulatory barriers to pain management now have been systematically identified in every state. A profile for every state is available on the web site of the Pain & Policy Studies Group (www.medsch.wisc.edu/painpolicy).

Progress has been made to remove regulatory barriers in some states, and also to adopt positive pain-related policies as reported in the 2000 Annual Review of State Pain Policies.[27] Eight states have adopted the model guidelines from the Federation of State Medical Boards.[28] Ten additional states have adopted it in part. The Initiative recommends that all state medical boards consider adopting or adapting the model guideline of the Federation of State Medical Boards in cooperation with pharmacy and nursing boards. They then should educate their licensees to clarify that pain management is encouraged, that it is a part of good professional practice, and that there is nothing to fear if opioids are prescribed, dispensed, or administered in accordance with evidence-based guidelines.

To promote balanced state regulations and policies relating to pain management, the SCCPI sponsored a statewide conference that brought together members from regulatory boards and law enforcement. This type of conference provides a forum for healthcare professionals, patients, and others to share their concerns regarding pain management.

The Maine Cancer Pain Initiative, a committee of the Maine Hospice Council, frequently advocates for health policy initiatives that are consistent with its mission of improving pain management. The most recent legislative efforts of the Maine Cancer Pain Initiative/Maine Hospice Council involved defeating a referendum for physician-assisted suicide and passing legislation to improve end-of-life care.

Building on the momentum of a pain summit sponsored by the Commonwealth of Virginia in 1996, the Virginia Cancer Pain Initiative successfully advocated for three legislative proposals to improve state law pertaining to healthcare access. The legislation, which is now law, does the following: 1) provides access to hospice services through health maintenance organizations and insurance companies; 2) requires reimbursement by private insurers for cancer pain medications and access to pain specialists and oncologists without a referral when pain is the primary problem; and 3) establishes a state-sponsored palliative care study. The Virginia Cancer Pain Initiative also partnered with the Virginia Department of Health and 40 other agencies to develop and promote a 5-year Cancer Control Plan for the Commonwealth of Virginia. This partnership has ensured that pain management is incorporated into the foundation of this statewide plan.

Conclusion

The greatest strengths of the CPIs are the following: 1) the presence of committed leadership with expertise and passion for the mission; 2) their ability to collaborate and network with others who share common goals; and 3) the interdisciplinary nature of their programs. These strengths must be enhanced as the state CPIs enter the next phase of their work. Inspired by the end-of-life care movement and the new pain standards from the Joint Commission on Accreditation of Health Care Organizations, many CPIs have expanded their public and professional education programs, increased public and patient awareness of the importance of pain management, and had a positive impact in the legislative and regulatory arenas. Yet, challenges remain. The recent media attention on the unfortunate abuse of Oxycontin (Purdue Pharma LP, Stamford, CT) is reinforcing myths and misconceptions about opioids that CPIs have worked hard to eliminate.

There appears to be no reduction in the need for these state-based organizations. While CPIs have historically focused on cancer pain, there is increasing recognition of the need to expand the movement to embrace all kinds of pain. The current crisis in healthcare delivery is likely to enhance the need for independent, forceful advocacy groups to promote adequate pain relief for all persons.

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References

1. Daut RI, Cleeland CS. The prevalence and severity of pain in cancer. *Cancer.* 1982;50:1913–1918.
2. Von Roenn JH, Cleeland CS, Gonin R, Hatfield, AK, Pandya KJ. Physician attitudes and practice in cancer pain management: a survey of the Eastern Cooperative Oncology Group 1993;119: 121–126.
3. Cleeland CS, Gonin R, Hatfield AK, et al. Pain and its treatment in outpatients with metastatic cancer. *N Engl J Med.* 1994; 330:592–596.
4. Bernabei R, Gambassi G, Lapane K, et al. Management of pain in elderly patients with cancer. *JAMA.* 1998;279:1877–1882.
5. Wolfe J, Grier HE, Klar N, et al. Symptoms and suffering at the end of life in children with cancer. *N Engl J Med.* 2000;342: 326–333.
6. Weiss SC, Emanuel LL, Fairclough DL, Emanuel EE. Understanding the experience of pain in terminally ill patients. *Lancet.* 2001;357:1311–1315.
7. Redford GD. Their final answers: an exclusive modern maturity survey. *Modern Maturity.* 2000; 43W September-October: 66, 68.
8. Cleeland CS. Barriers to the management of cancer pain. *Oncology.* 1987;April(suppl):9–26.
9. Ward SE, Goldberg N, Miller-McCauley V, et al. Patient-related barriers to management of cancer pain. *Pain.* 1993;52:319–324.
10. Pargeon KL, Hailey BJ. Barriers to effective cancer pain management: a review of the literature. *J Pain Symptom Manage.* 1999;18:358–368.
11. Greene PE. America responds to cancer pain: a survey of state initiatives. *Cancer Pract.* 1993;1:65–73.
12. Dahl JL. State cancer pain initiatives. *J Pain Symptom Manage.* 1993;8:372–375.
13. Dahl JL. State cancer pain initiatives: a decade of progress. *Cancer Prev Int.* 1998;3:157–164.
14. Dahl JL, Joranson DE, Engber D, Dosch J. The cancer pain problem: Wisconsin's response. *J Pain Symptom Manage.* 1988;3:S1–S20.
15. Dahl JL. The state cancer pain initiatives form a national organization: The American Alliance of Cancer Pain Initiatives. *APS Bull.* 1996;6:3.
16. Spross JA, McGuire DB, Schmitt RM. Oncology Nursing Society position paper on cancer pain. *Oncol Nurs Forum.* 1991;17: 595–614, 751–760, 943–955.
17. American Society of Clinical Oncology Ad Hoc Committee on Cancer Pain. Cancer pain assessment and treatment curriculum guidelines. *J Clin Oncol.* 1992;101:1976–1982.
18. Jacox AK, Carr DB, Payne R, et al. *Management of Cancer Pain, Clinical Practice Guideline, No. 9.* Rockville, Md: US Department of Health and Human Services, Public Health Service, Agency for Health Care Policy and Research; 1994; AHCPR Publication No. 94-0592.
19. Gibson R. The Robert Wood Johnson Foundation grant-making strategies to improve end-of-life care. *J Palliat Med.* 1998;1: 415–417.
20. The American Cancer Society. *Implementing Pain Management Initiatives: A Resource Book for Divisions.* Atlanta, Ga: American Cancer Society; 2001.
21. Weissman DE, Dahl JL, Beasley JW. The cancer pain role model program of the Wisconsin Cancer Pain Initiative. *J Pain Symptom Manage.* 1993;8:29–35.
22. Ferrell BR, Grant M, Ritchey KJ, et al. The pain resource nurse training program: a unique approach to pain management. *J Pain Symptom Manage.* 1993;9:549–556.
23. Dahl JL. New JCAHO standards focus on pain control. *Oncol Issues.* 1999;14:27–28.
24. Berry PH, Dahl JL. The new JCAHO pain standards: implications for pain management nurses. *Pain Manage Nurs.* 2000; 1:3–12.
25. Bill Moyers. *On Our Own Terms: Moyers on Dying in America: Leadership Guide.* Available at: **www.pbs.org/wnet/onourownterms**. Accessed September 2001.
26. National Association of State Controlled Substances Authorities. *Resolution 87-11: Use of Controlled Substances for Legitimate Medical Purposes.* Williamsburg, Va: National Association of State Controlled Substances Authorities; 1987.
27. Pain and Policy Studies Group. *A Guide to Evaluation: Achieving Balance in Federal and State Pain Policy.* Madison, Wis: University of Wisconsin-Madison; 2000.
28. Federation of Medical Boards of the United States. *Model Guidelines for the Use of Controlled Substances for the Treatment of Pain.* Euless, TX: Federation of Medical Boards of the United States. May 1999.

Special Article

Pain Management, Controlled Substances, and State Medical Board Policy: A Decade of Change

David E. Joranson, MSSW, Aaron M. Gilson, PhD, June L. Dahl, PhD, and J. David Haddox, DDS, MD

Pain & Policy Studies Group, University of Wisconsin-Madison, Comprehensive Cancer Center, and World Health Organization Collaborating Center for Policy and Communications (D.E.J., A.M.G.), Madison, Wisconsin; Department of Pharmacology (J.L.D.), University of Wisconsin-Madison, Medical School, Madison, Wisconsin; and Purdue Pharma LP (J.D.H.) Stamford, Connecticut, USA

Abstract

Physicians' concerns about regulatory scrutiny and the possibility of unwarranted investigation by regulatory agencies negatively affect their prescribing of opioid analgesics to treat pain. Indeed, some state medical boards have rejected prescribing practices that are considered acceptable by today's standards. This article describes a ten-year program of research, education, and policy development implemented by the Pain & Policy Studies Group aimed at updating and clarifying state medical board policies on the use of opioid analgesics to treat pain, including cancer and chronic noncancer pain. Following surveys of medical board members and educational workshops, state medical board policies began an initial period of change, drawing on guidelines from other states, particularly in California. The next phase of policy development was marked by the introduction of Model Guidelines by the Federation of State Medical Boards of the U.S. The Model Guidelines address professional standards for the appropriate prescribing of opioid analgesics for pain management, as well as physicians' fears of regulatory scrutiny. Although most state medical boards have adopted regulations, guidelines, or policy statements relating to controlled substances and pain management, to date ten boards have adopted the Model Guidelines, while ten more have adopted the Model Guidelines in part. Further actions are recommended so that state medical boards can address inadequate pain management and physician concerns about regulatory scrutiny. J Pain Symptom Manage 2002:23:138–147. *© U.S Cancer Pain Relief Committee, 2002.*

Key Words

Medical boards, pain policy, chronic pain, cancer pain, opioids

Introduction

There are many safe and effective treatments for pain, both pharmacologic and non-pharmacologic. Clinical practice guidelines, as well as other authoritative sources, emphasize that opioid analgesics are essential for the treatment of moderate to severe pain, especially acute pain[1,2] and cancer pain.[2–4] In addition, there is a growing consensus that opioids can be appropriate for certain patients with chronic noncancer pain if there is proper evaluation and monitoring of pain relief and functional out-

Address reprint requests to: David E. Joranson, MSSW, Pain Policy Studies Group, 406 Science Drive, Suite 202, Madison, WI 53711 USA

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3. Mcvers OL, Jessop S, Klemp P. The epidemiology of rheumatic disease in a rural and an urban population over the age of 65 years. S Afr Med J 1982;62:403–405.

4. Waddell G. Low back pain: A twentieth-century health care enigma. Paper presented at the Proceedings of the 8th World Congress on Pain, 1997; Vienna.

5. Bell JR. Australian trends in opioid prescribing for chronic non-cancer pain, 1986–1996. Med J Aust 1997;167:26–29.

6. Truter I. Patterns of analgesic prescribing in a South African primary care setting. J Clin Pharm Ther 1997;22:33–37.

7. Antonov KI, Isacson DG. Prescription and nonprescription analgesic use in Sweden. Ann Pharmacother 1998;32:485–494.

8. Brookoff D. Chronic pain: 2. The case for opioids. Hosp Pract (Off Ed) 2000;35:69–72.

9. Portenoy RK. Current pharmacotherapy of chronic pain. J Pain Symptom Manage 2000;19:S16–20.

10. Savage SR. Opioid therapy of chronic pain: assessment of consequences. Acta Anaesthesiol Scand 1999;43:909–917.

11. Bannwarth B. Risk-benefit assessment of opioids in chronic noncancer pain. Drug Saf 1999;21:283–296.

12. Parrott T. Using opioid analgesics to manage chronic noncancer pain in primary care. J Am Board Fam Pract 1999;12:293–306.

13. Dellemijn PL, van Duijn H, Vanneste JA. Prolonged treatment with transdermal fentanyl in neuropathic pain. J Pain Symptom Manage 1998;16: 220–229.

14. Jamison RN, Raymond SA, Slawsby EA, et al. Opioid therapy for chronic noncancer back pain. A randomized prospective study. Spine 1998;23:2591–2600.

15. Peloso PM, Bellamy N, Bensen W, et al. Double blind randomized placebo control trial of controlled release codeine in the treatment of osteoarthritis of the hip or knee. J Rheumatol 2000;27:764–771.

16. Roth SH, Fleischmann RM, Burch FX, et al. Around-the-clock, controlled-release oxycodone therapy for osteoarthritis-related pain: placebo-controlled trial and long-term evaluation. Arch Intern Med 2000;160:853–860.

17. Schofferman J. Long-term opioid analgesic therapy for severe refractory lumbar spine pain. Clin J Pain 1999;15:136–140.

18. Rapp SE, Wild LM, Egan KJ, Ready LB. Acute pain management of the chronic pain patient on opiates: a survey of caregivers at university of washington medical center. Clin J Pain 1994;10:133–138.

19. Simpson RK Jr, Edmondson EA, Constant CF, Collier C. Transdermal fentanyl as treatment for chronic low back pain. J Pain Symptom Manage 1997;14:218–224.

20. California TMBO. Guideline for prescribing controlled substances for intractable pain. Medical Board of California Action Report 1994;51:1–8.

21. Passik SD, Schreiber J, Kirsh KL, Portenoy RK. A chart review of the ordering and documentation of urine toxicology screens in a cancer center: do they influence patient management? J Pain Symptom Manage 2000;19:40–44.

22. Gloth FM 3rd. Geriatric pain. Factors that limit pain relief and increase complications [in process citation]. Geriatrics 2000;55:46–48.

23. Zenz M. Morphine myths: sedation, tolerance, addiction. Postgrad Med J 1991;67:S100–102.

24. Greenwald BD, Narcessian EJ, Pomeranz BA. Assessment of physiatrists' knowledge and perspectives on the use of opioids: review of basic concepts for managing chronic pain. Am J Phys Med Rehabil 1999;78:408–415.

25. Pappagallo M, Heinberg LJ. Ethical issues in the management of chronic nonmalignant pain. Semin Neurol 1997;17:203–211.

26. Chabal C, Erjavec MK, Jacobson L, et al. Prescription opiate abuse in chronic pain patients: clinical criteria, incidence, and predictors. Clin J Pain 1997;13:150–155.

comes.[5–7] Despite the availability of such treatments, inadequate management of pain has been found in patients with a variety of diagnoses and conditions[8–12] and in a variety of health-care settings.[13–19]

It is well-documented that many factors, or barriers contribute to inadequate treatment of pain; among these are physicians' fears of being investigated for prescribing opioids.[20–24] Studies have demonstrated that physicians underprescribe opioid analgesics out of fear of state board disciplinary action, even though prescribing opioids for pain management is legitimate if done in the course of professional practice. Apprehension on the part of physicians seems warranted by evidence from a 1991 survey indicating that some members of state medical boards, the organizations that license and discipline physicians, appear to have attitudes and beliefs that conflict with the use of opioids for treatment of pain.[25] These attitudes may be reflected in the policies issued by a state medical board, as well as in a board's enforcement procedures. Indeed, some board policies have contained statements and recommendations that discourage the use of opioid analgesics for pain management.

There is a need for state medical boards to adopt policies that encourage adequate pain management and dispel physicians' fears of being disciplined, in keeping with accepted medical practice. Adoption and dissemination of such policies can play an important role in modifying physicians' knowledge, beliefs, and practices concerning the treatment of pain with opioid analgesics. It is important to note that national organizations such as the American Medical Association[26] and the Federation of State Medical Boards in the United States (FSMB)[27] have advocated a non-legislative approach to promoting the use of controlled substances for pain management, which is the focus of this paper. In addition, some state statutes may hinder appropriate pain management by containing additional restrictions or requirements on prescribing opioid analgesics,[28–29] superceding the authority of state medical boards to regulate medical practice.[27]

Over the last decade, a program of research, education and policy evaluation was undertaken by the Pain Policy Studies Group (PPSG) with state medical boards and national pain associations to address physicians concerns about regulatory scrutiny. The program was developed in several stages, beginning with a national survey of state medical board members and followed by educational workshops for board members, evaluation of medical board policies, and technical assistance to develop model state medical-regulatory guidelines for the use of controlled substances in pain management. Taken together, these efforts demonstrate that regulatory agencies are making efforts to recognize the importance of pain management with opioids, for cancer and non-cancer conditions.

Physician Concern About Regulatory Scrutiny

A 1990 survey of oncologists studied the reasons for inadequate cancer pain management and found that 18% rated excessive regulation of analgesics as one of the top four barriers.[30] Indeed, oncologists in several states had been investigated and prosecuted for prescribing opioids to cancer patients (who were by then deceased). Eventually the charges were dismissed, but these events reached the news media, including being described in a cancer journal.[31]

A 1991 survey of Wisconsin physicians found that more than half would at least occasionally reduce dose, quantity or refills, or prescribe a drug in a lower schedule due to fear of regulatory scrutiny.[32] These physicians' concerns about investigation were least when opioids were prescribed for acute pain, but increased if prescribing was for chronic cancer pain; concern was greatest if prescribing was for chronic pain not related to cancer, or for patients with a history of drug abuse.

In that same year, 40% of surveyed physician-members of the American Pain Society (APS) said that concerns about regulatory scrutiny, rather than medical reasons, led them to avoid prescribing opioids for chronic non-cancer pain patients.[33] In a national survey of physicians, some respondents reported that regulatory pressure restricted their use of opioids for patients with chronic non-cancer pain.[23] Indeed, the use of opioid analgesics for chronic non-cancer pain has been controversial[6,34,35] and actively discouraged by some in both the pain and regulatory communities. More recently, clinicians, researchers, and regulators have be-

gun to reexamine the use of opioids for chronic non-cancer pain, including treatment efficacy, potential of adverse pharmacologic effects, and abuse and addiction liability, concluding that there is a role for opioids in carefully-selected patient populations.[5–7,36,37]

Research and Education with State Medical Boards

In response to these findings, in 1991 the PPSG surveyed all the members of state medical boards to assess whether board members' knowledge and attitudes could pose a threat to physicians who prescribe opioids for management of chronic cancer and non-cancer pain.[25] With the cooperation of the FSMB, a confidential pre-tested questionnaire was mailed to all 627 state medical board members in the U.S. A 50% response rate was achieved. Respondents represented 49 states, with a mean of six respondents per state. Physicians, public members, and other health-care practitioners were surveyed; 79% of the respondents were physicians and 15% were public members.

To directly address the validity of physicians' fears of regulatory scrutiny, board members were asked their opinions about the legality and medical acceptability of prescribing opioids for more than several months to patients with different diagnoses, including a patient with chronic cancer pain and a patient with chronic non-cancer pain. The respondent could indicate whether the prescribing practice was: (1) lawful and generally acceptable medical practice, (2) lawful but generally not acceptable and should be discouraged, (3) probably a violation of state medical laws or regulations and should be investigated, (4) probably a violation of federal or state controlled substances laws and should be investigated, or (5) that the respondent did not know the legality of extended opioid prescribing. It is important to note that, while federal drug enforcement policy recognizes that the use of opioids for pain including for patients with chronic disorders is lawful, it remains the province of the states to determine what constitutes legitimate medical practice.[21,38,39]

While most respondents agreed that the prescribing of opioids for the cancer patient was legal and generally acceptable medical practice, only 12% were confident in the legality of prescribing for the patient with chronic non-cancer pain; the majority of respondents (77%) would discourage this practice or even investigate it as a violation of law. It is of interest that the median year in which the physician-board members received their medical training was 1961, before pain treatment became a clinical science, before pain relief had become a public health priority, and well before the growing recognition that opioids could be used for patients with chronic non-cancer pain. There were also deficiencies in board members' knowledge about the extent to which cancer pain can be relieved, appropriate pharmacologic treatments for moderate to severe cancer pain, and the meaning and incidence of addiction when opioids are used to manage pain. Public members were more likely to indicate that they did not know the answers to survey items.

The survey results showed a clear need to update medical board members' knowledge about pain management and public policy. The findings were published in the FSMB journal, the *Federation Bulletin*,[25] in order to further a working relationship aimed at education, policy evaluation, and future research with the medical boards. The PPSG initiated a series of seminars for board members, believing that they would want to know about recent developments in pain management, and that they would respond to other physicians' concerns about being investigated for prescribing to treat chronic pain.

The PPSG and the FSMB cosponsored a series of 11 workshops on "Pain Management in a Regulated Environment" between 1994 and 1998. The faculty for all workshops was consistent, and included experts in pharmacology, pain medicine, addiction medicine, and public policy. Workshop content included the extent of the pain problem, the reasons for inadequate management of pain including exaggerated fear of addiction and concerns about regulatory scrutiny, methods for the assessment and treatment of pain, a review of recent advances in the understanding of pain physiology and opioid pharmacology, and the status of federal and state controlled substances and professional practice law, regulations, and medical board guidelines about the use of controlled substances for pain management.[40]

A total of 297 representatives of state medical boards signed up to participate in any one of the 11 one-day workshops; the participants

represented 40 states and approximately 25% of the total board member population.[40] Participants in the workshops included both physician and public members, as well as some investigators, attorneys, and administrative staff. All participants completed a pre-test, post-test, and follow-up survey to evaluate changes in knowledge and attitudes as a result of their involvement in the workshops.[40]

Evaluation of State Medical Board Policy

In the next phase of the program, the quality of state medical board policies was evaluated to better understand the potential for these policies to pose a threat to physicians who prescribe controlled substances for pain management. Medical board policies and guidelines express the attitude of the board regarding controlled substances and pain management. By 1990, few medical boards had adopted policies relevant to controlled substances and the treatment of pain; most of these early policies were eventually superceded by new policies.[28] By 2000, more than half of the state medical boards had adopted pain guidelines (see Fig. 1). The full text for the medical board policy in each state can be found at: http://www.medsch.wisc.edu/painpolicy/matrix.htm.

A team analysis approach[41] with three researchers was used to evaluate guidelines and policy statements that had been adopted in 24 states between 1989 and 1997, the most recent year for which policies were available when this study was begun (see Table 1). Each policy was rated according to several criteria, including whether the guidelines: (1) contained a stated purpose to address concerns about regulatory scrutiny, encourage pain management, and encourage physicians to become knowledgeable about pain management; (2) recognized the medical use of opioids for pain, including chronic non-cancer pain; and (3) recognized that certain restrictions or requirements could interfere with prescribing opioids for pain management.

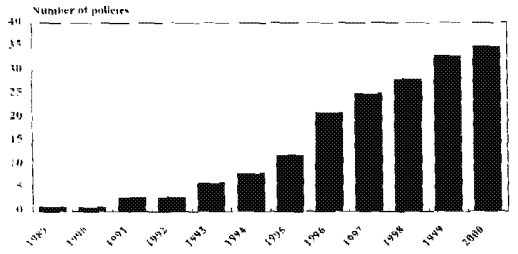

Fig. 1. The cumulative trend in the number of pain management or controlled substances policies adopted by state medical boards in the United States from 1989 to 2000.

The raters' evaluations of the items found in each policy were compared to determine the extent of discrepancy, i.e., when raters had different responses. There was an initial agreement of 86% among raters, suggesting high "reproducibility" (p. 17).[42] For each discrepancy, the reasons were determined and a consensus was achieved and recorded. Percentages were calculated to represent the extent that each item was present in each policy.

Stated Purpose of the Policy

Fifty-four percent of the 24 policies (13 states) recognized physicians' concerns about regulatory scrutiny but only 33% (8 states) actually addressed the concerns by providing guidelines or principles the board uses to distinguish legitimate from questionable prescribing practices. Thirty-eight percent of the guidelines (9 states) included statements that encouraged pain management; 46% (11 states) provided physicians with sources of information about pain management, such as the Agency for Health Care Policy and Research clinical practice guidelines or the consensus statement by the APS and the American Academy of Pain Medicine (AAPM).

Recognition of Medical Uses for Opioids

Thirty-eight percent of the guidelines (9 states) recognized the appropriateness of using opioids for cancer pain; 46% (11 states) recognized that opioids may be used for chronic non-cancer

Table 1
Twenty-Four States Represented in Content Evaluation of Medical Board Policies

Alaska	Massachusetts	Rhode Island
Arizona	Minnesota	Tennessee
California	Montana	Texas
Colorado	New Mexico	Utah
Florida	North Carolina	Vermont
Georgia	Ohio	Washington
Idaho	Oklahoma	West Virginia
Maryland	Oregon	Wyoming

documentation, rather than on the quantity and chronicity of prescribing." (p. 2)

- "All physicians should become knowledgeable about effective methods of pain treatment. . . . Physicians are referred to the U.S. Agency for Health Care [Policy] and Research Clinical Practice Guidelines for a sound approach to the management of acute and cancer-related pain. The medical management of pain should be based on current knowledge and research and includes the use of both pharmacologic and non-pharmacologic modalities." (p. 1)

Source: Federation of State Medical Boards of the United States, Inc. *Model Guidelines for the Use of Controlled Substances for the Treatment of Pain*. Euless, TX, May 1998.

pain. For example, a medical board policy statement from North Carolina stated that:

> It should be understood that the Board rec-

the costs of treatment, and marginalize opioids as a treatment of last resort.

Nine guidelines (47%) appeared to man-

Guidelines are available on the FSMB Web site at http://www.fsmb.org. The Model Guidelines, endorsements of the Model Guidelines, as well as all state medical board policies and state laws governing the use of controlled substances for pain management, are available on the PPSG Web site at http://www.medsch.wisc.edu/painpolicy/matrix.htm.

Discussion

That physicians fear they will be investigated for writing excessive opioid prescriptions has been described as an "unwritten doctrine" (p. 257).[51] Although opioid analgesics have been regarded as the mainstay of treatment for pain related to surgery and trauma for many years, national encouragement of their use for cancer pain did not occur until more recently.[1–4] There is a growing consensus supporting the use of opioids in chronic non-cancer pain.[5,37] These changes, along with the advent of new information about pain physiology, opioid pharmacology, and revised conceptions of addiction and dependence, represent new knowledge that needs to be incorporated into medical education and practice.[52] It is essential that state medical policies adapt to these changes.

The Model Guidelines provide a carefully considered policy framework that can be used by state medical boards to accomplish this goal. However, many state medical boards have yet to adopt the new guidelines, as recommended by the FSMB.[27] Since May of 1998, ten state medical boards have adopted policies that are substantially the same as the Model Guidelines: Alabama, Florida, Kansas, Minnesota, Nebraska, Nevada, Pennsylvania, South Carolina, South Dakota, and Utah. In addition, another ten state medical boards have issued policies that use the Model Guidelines in part: Arizona, Kentucky, Louisiana, Maine, Missouri, New Hampshire, New York, Oklahoma, Tennessee, and West Virginia. Most of the medical boards from these states had at least one member participate in the workshops on "Pain Management in a Regulated Environment." Apparently, the workshops provided not only a rationale but an impetus for medical boards to develop policy to encourage pain management and to allay physicians' fears about regulatory scrutiny. Identifying all the catalysts for policy development by state medical boards will require further study.

Conclusions and Recommendations

Successful elimination of physician fear of regulatory scrutiny will depend in part on achieving more balanced controlled substances policies in each state (i.e., policies that aim not only to prevent drug abuse but also acknowledge the important medical uses of controlled substances, in particular the opioid analgesics).[20,53] The purpose is not to advocate the use of opioids for all pain, but to encourage effective pain management, including the use of opioids when appropriate.

We recommend that all state medical boards adopt guidelines or policy statements (rather than statutes) on the use of controlled substances for pain management, and ensure that investigation and discipline of physicians is consistent with board policy and does not interfere with pain management. New state board guidelines should be based on the FSMB Model Guidelines. They should be disseminated to all licensed physicians, and publicized through the boards' Web sites, newsletters, and press releases. In addition, we urge that medical boards cooperate with state boards of pharmacy and nursing to coordinate and establish policies that reflect a consensus of health-care professionals, as has been done in Washington, North Carolina, West Virginia, and Kansas. Alternatively, physicians could work with their medical society to develop pain management policies, which could then be endorsed by the state medical board.

We encourage state medical societies to organize educational programs for physicians that address pain management, regulatory requirements, medical board policies, and concerns about regulatory scrutiny. Medical boards can participate in such efforts, communicating directly with physicians and addressing their perceptions of risk.

Despite dissemination of guidelines to licensees, practitioners often remain unaware of new policies in their state.[48,54] Overcoming this communication gap requires attention to effective communication strategies. The North Carolina medical board has made great effort to communicate its pain guidelines, and has sponsored educational programs about pain

and end-of-life care for both the public and professionals. Most medical boards have little in the way of educational resources and will need support. One strategy has been employed by the Alabama Board of Medical Examiners through joint sponsorship of educational events with the state medical society. Approximately 75% of medical boards have sponsored Web sites and newsletters; these can be used to inform licensed practitioners of the board's policy to encourage pain management.

If the collective efforts of the pain management and regulatory communities do not make significant progress to eliminate fears of regulatory scrutiny, frustration with physicians who do not provide adequate pain management will mount and may lead to policies that penalize *inadequate* pain management. Such policies have already been discussed by the Institute of Medicine and state medical boards.[22,52] Indeed, the Oregon Board of Medical Examiners disciplined a physician for inadequate pain management.[55] In lieu of license revocation, the Oregon Board required the physician to participate in an intensive educational curriculum about pain management.

We believe that education, not discipline, should be the cornerstone of efforts to improve pain management. However, it is axiomatic that if pain management is to be an expected part of quality medical practice, then substandard pain management practice must be subject to review and corrective action as in any other area of medical practice.

The trends in state medical board policies reported here are a reflection of increasing concern about inadequate pain management. Making real improvements in pain management will require the proactive efforts of many organizations. The contribution of state medical boards and other regulatory agencies is a welcome addition.

Acknowledgments

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References

1. Acute Pain Management Guideline Panel. Acute Pain Management: Operative or Medical Procedures and Trauma. Clinical Practice Guideline. AHCPR Pub. No. 92-0032. Rockville, MD: Agency for Health Care Policy and Research. Public Health Service, U.S. Department of Health and Human Services; February 1992.

2. American Pain Society. Principles of Analgesic Use in the Treatment of Acute Pain and Cancer Pain, 4th ed. Glenview, IL; 1999.

3. World Health Organization. Cancer Pain Relief. Geneva, Switzerland: WHO; 1986.

4. Jacox A, Carr DB, Payne R et al. Management of Cancer Pain. Clinical Practice Guideline. No. 9. AHCPR Publication No. 94-0592. Rockville, MD: Agency for Health Care Policy and Research, Public Health Service, U.S. Department of Health and Human Services; March 1994.

5. American Academy of Pain Medicine and American Pain Society. The Use of Opioids for the Treatment of Chronic Pain: A Consensus Statement. American Academy of Pain Medicine and American Pain Society; 1997.

6. Portenoy RK. Opioid therapy for chronic nonmalignant pain: clinicians' perspective. J Law, Med & Ethics 1996;24(4):296–309.

7. American Medical Association Council on Scientific Affairs. Report 11 of the Council on Scientific Affairs: Use of Opioids in Chronic Noncancer Pain. Chicago, IL: American Medical Association; 1999.

8. Bernabei R, Gambassi G, Lapane K, et al. Management of pain in elderly patients with cancer. JAMA 1998;279:1877–1882.

9. Cleeland CS, Gonin R, Hatfield AK, et al. Pain and its treatment in outpatients with metastatic cancer. N Engl J Med. 1994;330:592–596.

10. Breitbart W, Rosenfeld BD, Passik SD, McDonald MV, Thaler H, Portenoy RK. The undertreatment of pain in ambulatory AIDS patients. Pain 1996;65(2–3):243–249.

11. Whipple JK, Lewis KS, Quebbeman EJ, et al. Analysis of pain management in critically ill patients. Pharmacotherapy 1995;15(5):592–599.

12. Zhukovsky DS, Gorowski E, Hausdorff J, Napolitano B, Lesser M. Unmet analgesic needs in cancer patients. J Pain Symptom Manage 1995;10(2):113–119.

13. SUPPORT Study Principle Investigators. A controlled trial to improve care for seriously-ill hospitalized patients: The study to understand prognoses and preferences for outcomes and risks of treatments (SUPPORT). JAMA 1995;274:1591–1598.

14. Nowels D, Lee JT. Cancer pain management in home hospice settings: a comparison of primary care and oncology physicians. J Pall Care 1999; 15(3):5–9.

15. Tanabe P, Buschmann M. A prospective study of ED pain management practices and the patient's perspective. J Emerg Nursing 1999;25(3):171–177.

16. Smith BH, Hopton JL. Chambers WA. Chronic pain in primary care. Fam Prac 1999;16(5):475–482.

17. Ferrell BR, Juarez G, Borneman T. Use of routine and breakthrough analgesia in home care. Oncol Nurs Forum 1999;26(10):1655–1661.

18. Kruger M, McRae K. Pain management in cardiothoracic practice. Surg Clinics North Amer 1999; 79(2):387–400.

19. Stevens DS, Edwards WT. Management of pain in intensive care settings. Surg Clinics North Amer 1999;79(2):371–386.

20. Hill CS Jr. The negative effect of regulatory agencies on adequate pain control. Prim Care Cancer 1989;November:45–53.

21. Joranson DE, Gilson A. Controlled substances, medical practice, and the law. In: Schwartz HI, ed. Psychiatric Practice Under Fire: The Influence of Government, the Media, and Special Interests on Somatic Therapies. Washington, DC: American Psychiatric Press; 1994:173–194.

22. Martino AM. In search of a new ethic for treating patients with chronic pain: What can medical boards do? J Law, Med & Ethics 1998;26(4):332–334.

23. Turk DC, Brody MC, Okifuji FA. Physicians' attitudes and practices regarding the long-term prescribing of opioids for non-cancer pain. Pain 1994; 59:201–208.

24. American Medical Association Council on Scientific Affairs. Report 4 of the Council on Scientific Affairs: Aspects of Pain Management in Adults. Chicago, IL: American Medical Association; 1995.

25. Joranson DE, Cleeland CS. Weissman DE, Gilson AM. Opioids for chronic cancer and non-cancer pain: A survey of state medical board members. Available at http://www.medsch.wisc.edu/painpolicy/publicat/92jmldo.htm. Fed Bull 1992;79(4):15–49.

26. American Medical Association House of Delegates. Protection for Physicians Who Prescribe Pain Medication. Chicago, IL: American Medical Association; 1997.

27. Federation of State Medical Boards of the United States, Inc. Position of the Federation of State Medical Boards in Support of Adoption of Pain Management Guidelines. Euless, TX; February 2000. Available at http://www.medsch.wisc.edu/painpolicy/domestic/FSMBwp.htm.

28. Joranson DE, Gilson AM. State intractable pain policy: Current status. Available at http://www.medsch.wisc.edu/painpolicy/publicat/97apssi.htm. APS Bull. 1997;7(2):7–9.

29. Joranson DE, Gilson AM, Ryan KR, Maurer MA, Nelson JM, Nischik JA. Achieving Balance in Federal and State Pain Policy: A Guide to Evaluation. Madison, WI: Pain & Policy Studies Group: 2000. Available at http://www.medsch.wisc.edu/painpolicy/eguide2000.

30. Von Roenn JH, Cleeland CS, Gonin R., et al. Physician attitudes and practice in cancer pain management: A survey from the Eastern Cooperative Oncology Group. Annals Intern Med 1993;119(2):121–126.

31. McIntosh H. Regulatory barriers take some blame for pain undertreatment. J Nat Cancer Inst 1991;83(17):1202–1204.

32. Weissman DE, Joranson DE, Hopwood MB. Wisconsin physicians' knowledge and attitudes about opioid analgesic regulations. Wisc Med J. 1991;December:53–58.

33. Turk DC, Brody MC. What position do APS's physician members take on chronic opioid therapy? APS Bull 1992;2:1–5.

34. Portenoy RK. Therapeutic use of opioids: Prescribing and control issues. In: Cooper JR, Czechowicz DJ. Molinari SP, eds. Impact of Prescription Drug Diversion Control Systems on Medical Practice and Patient Care. Division of Clinical Research, National Institute on Drug Abuse. NIDA Research Monograph 1993;131:35–50.

35. Joranson DE, Gilson AM. Regulatory barriers to pain management. Sem Nursing Onc 1998;14(2): 158–163.

36. Portenoy RK. Opioid therapy for chronic nonmalignant pain: A review of the critical issues. J Pain Symptom Manage 1996;11(4):203–217.

37. Federation of State Medical Boards of the United States, Inc. Model Guidelines for the Use of Controlled Substances for the Treatment of Pain. Euless, TX; May 1998.

38. Code of Federal Regulations. §1306.07(c).

39. Drug Enforcement Administration. Physician's Manual: An Informational Outline of the Controlled Substances Act of 1970. Washington D.C., U.S. Department of Justice; March 1990.

40. Gilson AM, Joranson DE. Controlled substances and pain management: Changing knowledge and attitudes of medical regulators. J Pain Symptom Manage 2001;21(3):227–237.

41. Olesen V, Droes N, Hatton D, Chico N, Schatzman L. Analyzing together: recollections of a team approach. In: Bryman A, Burgess RG, eds. Analyzing Qualitative Data. New York, NY: Routledge; 1994:111–128

42. Weber RP. Basic Content Analysis. 2nd edition. Newbury Park: Sage Publications; 1990.

43. North Carolina Board of Medical Examiners. Management of chronic non-malignant pain. Forum 1996;4:1–2.

44. State of Washington Department of Health. Guidelines for Management of Pain. Olympia, WA; April 1996.

45. State Medical Board of Ohio. Scheduled drug therapy including narcotics for chronic benign pain. Your Report. 1995;Spring-Summer:3–5.

46. California Medical Board. New, easy guidelines on prescribing. Action Report. 1994;51:1.

47. Monterroso MM, Gilson AM, Williams CM, Nelson JM, Joranson DE. A Comparison of State Medical Board Pain Guidelines with a National Model. Poster presented at the 16th annual American Pain Society conference. New Orleans, LA; October 1997.

48. Joranson DE, Gilson AM. Controlled substances and pain management: A new focus for state medical boards. Available at http://www.medsch.wisc.edu/painpolicy/publicat/98fedbul.htm. Fed Bull 1998; 85(2):78–83.

49. Good PM. The Drug Enforcement Administration and Proposed Model Guidelines for the Use of Controlled Substances in Pain Management. Presentation at the Federation of State Medical Boards Symposium on Pain Management and State Regulatory Policy. Dallas, TX; March 1998.

50. Weissman DE, Haddox JD. Opioid pseudoaddiction—an iatrogenic syndrome. Pain 1989;36:363–366.

51. Weissman DE. Do drug regulations affect medical practice? J Pain Symptom Manage 1992;7:257–258.

52. Institute of Medicine. Approaching Death: Improving Care at the End of Life. Washington, D.C.: National Academy Press; 1997.

53. Rich BA. A prescription for the pain: The emerging standard of care for pain management. William Mitchell Law Rev 2000;26(1):1–91.

54. Potter MB, Schafer S, Croughan-Minihane M. Opioids in the Treatment of Chronic Nonmalignant Pain: The Attitudes and Practices of Primary Care Physicians. Poster presented at the 17th annual American Pain Society conference. San Diego, CA; November 1998.

55. Barnett E. Roseburg doctor faces penalty on pain control. The Oregonian. March 27, 1999:1.

Clinical Note

Methadone and Fluconazole: Respiratory Depression By Drug Interaction

Yoko Tarumi, MD, Jose Pereira, MD, and Sharon Watanabe, MD
Palliative Care Program, Grey Nuns Community Hospital, Edmonton, Alberta, Canada

Abstract
A 60-year-old man with advanced gastric cancer achieved good pain control on a stable dose of methadone for 10 days. However, he developed respiratory depression 2 days after intravenous fluconazole was administrated for refractory oral candidiasis. Intravenous naloxone effectively reversed the respiratory depression. This case illustrates a significant interaction between methadone and fluconazole, and highlights the need for awareness of potential interactions between drugs used in palliative care. J Pain Symptom Manage 2002;23:148–153 © *U.S. Cancer Pain Relief Committee*, 2002.

Key Words
Methadone, fluconazole, drug interaction

Introduction

There is growing interest in methadone for the treatment of moderate to severe cancer pain. It is generally described as a second-line opioid when patients have not responded to or have developed intolerable adverse effects to first-line opioids such as morphine.[1–6] Because of its possible N-methyl-D-aspartate (NMDA) receptor antagonism, there is also interest in using it as a first-line opioid for the management of neuropathic pain, but this potential role still needs to be confirmed.

Methadone is known to have a long and highly variable half-life.[2–7] Although its equianalgesic dose ratio relative to morphine and other opioids is unclear, there is good evidence that with long-term dosing it is much more potent than morphine and that the dose ratio correlates strongly with the dose of the opioid in use just prior to the switch to methadone.[8] An appreciation of these characteristics has led to more prudent dosing regimens. Reports of serious adverse effects such as respiratory depression are therefore now infrequent.

As with any other drug, increased knowledge of methadone's metabolism and potential interactions with other drugs enables the clinician to use it more safely and effectively. A recent review by Bernard and Bruera has highlighted the importance of recognizing drug interactions in palliative care and the potential consequences of these interactions in pain management.[9] The following case illustrates a significant drug interaction between methadone and fluconazole and underscores the need for clinicians to be vigilant for such possible interactions in palliative care.

Case Report

A 60-year-old man with advanced adenocarcinoma of the stomach was admitted to our tertiary-level palliative care unit (TPCU) for man-

Address reprint requests to: Yoko Tarumi, MD, Palliative Care Program, Grey Nuns Community Hospital, 1100 Youville Drive West, Edmonton, Alberta T6L 5X8, Canada.

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Special Article

Pain Management and Prescription Monitoring

David E. Joranson, MSSW, Grant M. Carrow, PhD, Karen M. Ryan, MA, Linda Schaefer, BA, Aaron M. Gilson, PhD, Patricia Good, BA, John Eadie, MA, Susan Peine, and June L. Dahl, PhD

Pain & Policy Studies Group (D.E.J., K.M.R., A.M.G.), University of Wisconsin Comprehensive Cancer Center, Madison, Wisconsin; Drug Control Program (G.M.C.), Massachusetts Department of Public Health, Jamaica Plain, Massachusetts; Texas Department of Public Safety (L.S.), Austin, Texas; Office of Diversion Control (P.G.), U.S. Drug Enforcement Administration, Arlington, Virginia; School of Public Health, State University of New York (J.E.), Albany, New York; Office of Diversion Control (S.P.), U.S. Drug Enforcement Administration, Arlington, Virginia; and Department of Pharmacology (J.L.D.), University of Wisconsin, Madison, Wisconsin, USA

Abstract

Preventing diversion and abuse of prescription controlled substances while ensuring their availability for legitimate medical use is an important public health goal in the United States. In one approach to preventing and identifying drug diversion, 17 states have implemented prescription monitoring programs (PMPs) to monitor the prescribing of certain controlled substances. While PMPs are not intended to interfere with legitimate prescribing, some in the pain management community feel that they negatively affect prescribing for pain management. This article describes a collaborative project initiated by the Pain & Policy Studies Group that brought together regulatory and pain management representatives twice in 1998 to share perspectives and reconcile differing views on the effects of PMPs. The ultimate goals of this project are to provide accurate information to healthcare clinicians about PMPs, better define the balance between preventing drug diversion and providing pain management, and promote continued dialog and cooperation among the groups. J Pain Symptom Manage 2002;23:231–238. © *U.S. Cancer Pain Relief Committee, 2002.*

Key Words

Prescription monitoring programs, triplicate prescriptions, single-copy serialized prescriptions, multiple copy prescriptions, electronic transmission, pain management, controlled substances, opioid analgesics, drug diversion, prescription drug abuse

Introduction

Undertreatment of pain is a major public health issue in the United States.[1–8] There are many safe and effective ways to treat pain. Drug therapy with opioid analgesics plays an important role in pain management and should be available when needed for the treatment of acute pain and chronic cancer, as well as non-cancer, pain.[5,9–11] Clinicians should be knowledgeable about using opioids to treat pain, and should not hesitate to prescribe them when opioids are the best clinical choice of treatment.[15] Because opioids have a potential for

Address reprint requests to: David E. Joranson, MSSW, Pain & Policy Studies Group, 406 Science Drive, Suite 202, Madison, WI 53711-1068, USA.

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abuse, they are controlled substances under federal and state law.[16,17] Practitioners must know and comply with federal and state laws and regulations, and exercise sound professional judgement when prescribing opioid analgesics to minimize diversion and abuse of these drugs.

Prescription Controlled Substances, Drug Abuse, and Diversion

The diversion of prescription controlled substances to illicit channels is a public health and safety issue. These medications are diverted in numerous ways, including theft, forgery, and counterfeiting of prescriptions; illegal sales of prescriptions and drugs; fraudulent activities that victimize physicians, pharmacies, and patients; and by a small percentage of physicians who write prescriptions indiscriminately because they are dishonest, disabled, deceived, or dated in their practices.[18–20] Misuse and abuse of prescription controlled substances can and does lead to serious health consequences, including "drug dependence, overdose and deaths."[18] There is a need for additional studies to document the amount of opioid analgesics that is diverted from prescriptions, or compare this source of diversion with other sources, such as from pharmacy thefts.[4] The nature and extent of prescription drug abuse has been reported by the Drug Enforcement Administration (DEA),[21] and the abuse trends of opioid analgesics have been evaluated.[22]

The Role of Law and Government Agencies

There is no question that it is legal under federal and state law for duly licensed and registered physicians, pharmacists, and nurses to prescribe, dispense, and administer controlled substances for legitimate medical purposes and in the usual course of professional practice. Although all state laws are based on this premise, the provisions may differ from state to state. The National Conference of Commissioners on Uniform State Laws (NCCUSL) provides a model act to which states can refer.[17]

State and federal government agencies respond not only to the diversion and abuse of opioids and other controlled substances, but also to the treatment needs of patients, including those in pain. Regulatory agencies endeavor to ensure that the professionals who care for ill and injured persons are qualified to do so. State governments examine and license healthcare professionals and facilities. The DEA and some states issue controlled substances registrations to state licensed practitioners for prescribing, dispensing, and administering controlled substances. State and federal agencies enforce security and record-keeping to protect the manufacture and supply of opioid medications, while the federal government ensures their continued availability by setting production quotas that satisfy legitimate medical needs. Regulatory agencies also work to reduce drug abuse through substance prevention, treatment programs, and law enforcement. They also investigate and take appropriate action when there is evidence of illegal activity, practitioner impairment, or incompetence.

Evolution of State Prescription Monitoring Programs

It is within this broad context that a number of states have established prescription monitoring programs (PMPs). Table 1 describes the current status of PMPs in the United States. Typically, PMPs collect prescribing and dispensing data from pharmacies, conduct review and analysis of the data, and disseminate it to appropriate regulatory and law enforcement agencies. Following the lead of New York State in the 1910s, California and Hawaii enacted PMPs in the 1940s. By the 1980s, seven more states had added PMPs. These early programs required that physicians use multiple copy forms (duplicate or triplicate) to write prescriptions for Schedule II controlled substances, and that pharmacists send one copy to the state after dispensing a drug. Physicians were usually required to obtain prescription forms from a state agency, and some states charged a fee for the forms. After verifying the practitioner's credentials, the relevant state agency issued the requested forms.

In the 1990s, some states initiated PMPs that rely solely on computer technology to collect data. In these states, a special prescription form is not required. Pharmacies use electronic transmission to enter and transmit electronically to the state the PMP information about

Table 1
States With Prescription Monitoring Program

State	Year of Program Enactment	Program Type	Schedules/Drugs Covered	Initial Program Type	Year of Initial Program Enactment
California	1996	Triplicate/electronic	C-II	Triplicate	1939
Hawaii	1996	Duplicate	C-II	Duplicate	1948
		Electronic	C-II, III, IV		
Idaho	1997	Duplicate	C-II	Triplicate	1967
		Electronic	C-II, III, IV		
Illinois	1999	Electronic	C-II	Triplicate	1961
Indiana	1994	Single-copy/electronic	C-II, III, IV, V	Triplicate	1987
Kentucky	1998	Electronic	C-II, III, IV, V		
Massachusetts	1992	Electronic	C-II		
Michigan	1993	Single-copy, serialized/electronic	C-II	Triplicate	1988
Nevada	1995	Electronic	C-II, III, IV		
New Mexico	1994	Electronic	C-II		
New York	1998	Single-copy, serialized/electronic	C-II and benzodiazepines	Triplicate	1972
Oklahoma	1990	Electronic	C-II		
Rhode Island	1997	Electronic	C-II, III	Duplicate	1978
Texas	1997	Single-copy, serialized/electronic	C-II,	Triplicate	1981
Utah	1995	Electronic	C-II, III, IV, V		
Washington	1981	Triplicate	C-II, III, IV, V		
West Virginia	1995	Electronic	C-II		

Note: Current as of 10/30/00; prescription monitoring programs are subject to change.
Sources: Drug Enforcement Administration, "Prescription Accountability Resource Guide," September 1998; and updated information obtained from states.

controlled substances prescriptions that have been dispensed.

With the advent of recent technological advances, states that used multiple copy prescription forms have modified their PMPs to include an electronic element. In addition, most of these states replaced their multiple copy forms with a single-copy, serially numbered form (Hawaii and Idaho use duplicate prescription forms with electronic transmission, and California uses triplicate forms concurrently with its electronic transmission system). Rhode Island and Illinois are the only states to completely repeal the requirement to use a special prescription form; both states now use electronic transmission exclusively. A model prescription accountability act, recommended by the National Alliance for Model State Drug Laws and the National Association of State Controlled Substances Authorities (NASCSA), provides for a system that combines electronic monitoring and a serialized prescription form.[23]

In practice, PMPs take different forms because each state government determines the goals, structure, and organization of its program. Currently, the PMPs are administered by professional boards, health departments, human services agencies, or consumer protection agencies in 12 of the states; and by justice departments, public safety agencies, or state police in the other five states. The manner in which a program is implemented depends on its stated goals, the mission of the responsible agency, and rules regarding access to the data.

Purpose of PMPs

The purpose of PMPs is to reduce the diversion of prescription controlled substances. Objectives of PMPs usually include: 1) education and information; 2) public health initiatives; 3) early intervention and prevention of diversion; and 4) investigations and enforcement.[20] Prescription monitoring is not intended to interfere with medical practice[24] and attempts are made to make it minimally intrusive (e.g., reducing the paperwork burden by replacing multiple copy forms with single-copy serialized forms or eliminating forms altogether). PMPs do not require physicians to obtain prior approval to issue prescriptions, nor do they impose limits on the quantity that may be prescribed. Although some state laws limit quantities that can be prescribed in one prescription, such limits are established by laws other than those that establish PMPs.[25] Regulatory agencies that are charged with enforcing the laws with respect to

drug diversion also recognize the legitimate need for controlled substances in medical care.[26]

PMPs enable law enforcement investigators to obtain prescription information quickly and efficiently, thereby reducing time and resources that would be otherwise expended in obtaining the information from individual practitioners or pharmacies. PMPs can also provide an efficient means of handling complaints, and can result in speedier resolution of pending cases, dismissal of unfounded complaints, and avoidance of unnecessary investigations. Aggregate data on prescribing trends from most PMPs is usually available for educational and research purposes. In all uses of the data, confidentiality of prescribers, pharmacies, and patients is protected, thereby meeting another goal of PMPs.[20]

State agencies indicate that a PMP can have a deterrent effect on potential criminal activities. Early intervention in illegal activities is one of the identified goals of these programs. For example, state authorities report that use of special prescription forms significantly reduces or eliminates prescription forgery. In addition, PMPs are especially useful for identifying "doctor shopping," scams, and illicit prescribing and dispensing. Drug abusers who are identified as doctor shoppers can be directed into drug treatment or prosecuted, depending on the circumstances of the case. PMPs take into account the possibility that persons who seek pain medications may be patients with inadequately treated pain.[27]

Concerns about PMPs

Preventing drug diversion and abuse, and ensuring the availability of drugs for medical purposes are often perceived as potentially incompatible goals. For example, there has been considerable debate between regulatory and medical groups about the requirement for government-issued prescription forms. During the 1980s and 1990s, representatives of the medical community expressed concerns that these special forms were an intrusion into medical practice and the doctor–patient relationship. They were concerned about being investigated and about the additional administrative burden associated with handling a special form for this class of medication. Federal and state agencies charged with administering controlled substances laws responded that the programs were effective in reducing drug diversion,[15] with minimal impact on legitimate medical practice.[21,24,28]

A number of publications have examined the effect of multiple copy forms on diversion and medical practice.[29–38] The National Institute on Drug Abuse and the Institute of Medicine have called for more definitive research in this area.[33,39] States have worked with their medical communities to address their concerns. States, such as New York and Texas, which are replacing multiple copy prescription forms with an official single-copy prescription form and electronic transmission, assert that prescribing on a single-copy form rather than a multiple copy form is intended to be closer to the use of ordinary prescription forms. While single-copy forms reduce paperwork handling, they retain the ability to prevent prescription forgery and counterfeiting.[19]

Representatives of the Alliance of States with Prescription Monitoring Programs ("the Alliance"), the states with PMPs, and the DEA stress to physicians that prescription monitoring data cannot and do not serve as prima facie evidence of illicit activities. PMP data can provide an indication of a possible problem that may require further inquiry. Further, the PMP administrators stress that it is their intention that PMPs be used to enforce state laws in a manner that is most supportive of, and least disruptive to, medical and pharmacy practice.

Collaboration Between Pain Management and Regulatory Groups

In 1998, the University of Wisconsin Pain & Policy Studies Group (PPSG) initiated a collaborative project with the DEA, the Alliance, and the Analgesic Regulatory Affairs Committee of the American Pain Society (APS) in order to exchange perspectives on PMPs and the prescribing of opioids for pain management. The goal of the project was to explore how the groups could cooperate to ensure appropriate care for patients in pain, while protecting the public from diversion of opioids to non-medical, illicit use. The immediate objectives were to:

- enhance cooperation between the DEA, state PMPs, and the pain management community

- better define the balance between the provision of opioid analgesic treatment to patients in pain and prevention of diversion of opioids into non-medical, illicit use
- provide information on these issues to the professionals who care for patients and administer controlled substances laws.

Meetings

The PPSG organized two meetings to bring together individuals from these groups. The first meeting was held at the University of Wisconsin in Madison, Wisconsin, on 20–21 July 1998. Fifteen people were invited; thirteen were able to attend. (The representatives at the July 1998 meeting were: For the Alliance—Grant Carrow, Massachusetts Department of Public Health; John Eadie, State University of New York; David Hale, Oklahoma Bureau of Narcotics; Linda Schaefer, Texas Department of Public Safety. For the APS—June Dahl, APS Analgesic Regulatory Affairs Committee; Aaron Gilson, Pain & Policy Studies Group; David Haddox, American Academy of Pain Medicine; David Joranson, Pain & Policy Studies Group; David Mackey, Mayo Clinic Jacksonville; Karen Ryan, Pain & Policy Studies Group. For the DEA—Patricia Good, Office of Diversion Control; Susan Peine, Office of Diversion Control. Other—Thomas D. Wyatt, Jr., National Association of State Controlled Substances Authorities. Unable to attend were: William Marcus, California Deputy Attorney General; Russell Portenoy, Beth Israel Medical Center.) The meeting began with a discussion of the perspectives held by each of the attendees. Following the exchange, it was evident to participants that, although there were misconceptions regarding some issues, there was a shared interest in improving pain management and preventing the diversion of prescription controlled substances. The participants prepared a list of the points of agreement.

The initial points of agreement were refined at a second meeting, held in Charleston, South Carolina, on 29 October 1998 during the annual meeting of NASCSA. (The attendees for the October 1998 meeting were: Grant Carrow, Massachusetts Department of Public Health; John Eadie, State University of New York; Patricia Good, Drug Enforcement Administration; David Hale, Oklahoma Bureau of Narcotics; David Joranson, Pain & Policy Studies Group; Susan Peine, Drug Enforcement Administration; Karen Ryan, Pain & Policy Studies Group; Linda Schaefer, Texas Department of Public Safety; Thomas D. Wyatt, Jr., National Association of State Controlled Substances Authorities.) The nine participants at the second meeting decided to write a jointly authored article about the collaboration, and to consider future publications regarding PMPs.

The initial perspectives offered by the participants provided guidance for subsequent discussions. The group reached consensus on seven issues for which brief descriptions follow: where the consensus involved future action, the progress to date is noted.

Consensus

1. Publications

The participants felt that it is imperative to provide accurate information to educate the medical community about the purpose and operation of PMPs. A jointly authored article describing the collaboration will be prepared for publication in a medical journal. In addition, information about PMPs will be prepared by the Alliance for dissemination to physicians, pharmacists, nurses, and regulators. Both publications should describe the common goals of the prescription monitoring and pain communities.

Progress. This article is a result of the collaboration between the PPSG, the Alliance, the APS, and the DEA. In addition, the Alliance has prepared a document detailing the goals of prescription monitoring.[20] The DEA has compiled information from the states into two publications: "Prescription Accountability Resource Guide"[24] and "Committee Report on Establishing a State Prescription Monitoring Program."[28] The DEA and the National Alliance for Model State Drug Laws have compiled additional information from the states for another publication: "Diversion and Abuse of Prescription Drugs: A Closer Look at State Prescription Monitoring Programs."[21]

2. FSMB Guidelines

Many states have adopted pain policies in recent years. Twenty states have adopted the Federation of State Medical Boards (FSMB) "Model

Guidelines for the Use of Controlled Substances for the Treatment of Pain in whole or in part."[40] In many states, controlled substance, health, and law enforcement agencies have endorsed the Guidelines.

Progress. Representatives at the meeting supported the FSMB's Model Guidelines. They have also been endorsed by the DEA and NASCSA, as well as by the APS and the American Academy of Pain Medicine (AAPM).

3. Resource Information

The participants recommended that state and federal officials and the pain management community increase their efforts to exchange information. For example, they advised that pain specialists be available to PMPs to consult on interpretation of data. Regulatory agencies receive calls from patients whose physicians will not prescribe adequate pain medication for them. The pain management community could assist these patients by providing referrals to physicians with appropriate training in pain management. The Alliance can be used as a resource for the pain management community by providing contacts and information on PMPs in general, or on specific states.

Progress. General information on PMPs, including state and federal contacts, is available from the Alliance (http://www.nascsa.org/monitoring.htm), and the DEA Diversion Control Program (http://www.deadiversion.usdoj.gov/pubs/program/index.html). In addition, the Alliance and the DEA serve as clearinghouses for specific questions or issues concerning PMPs.

4. Reciprocal Meetings

The participants recommended that representatives from the pain management and regulatory and law enforcement communities present and participate in each others' meetings in order to provide information and to address questions and misperceptions. This kind of exchange can increase understanding of mutual goals, provide an opportunity to communicate about issues that arise, and address practitioners' concerns about regulatory oversight.

Progress. Representatives of the DEA, the Alliance, and the FSMB have been invited to participate in national and state pain meetings to clarify issues related to prescription controlled substances, PMPs, and medical boards' disciplinary responsibilities. State agencies routinely provide speakers for meetings of their state's medical associations and societies. These presentations have been greatly appreciated by clinicians. NASCSA has invited representatives from the pain field to make presentations at its annual meetings. The groups should continue these cooperative endeavors.

5. Scam Alerts

Information on the most recently identified "scams" should be included on the DEA's web page and in the APS Bulletin.

Progress. The DEA's website contains recent information on scams being used to procure prescription controlled substances illegally. It is available on the DEA web pages http://www.deadiversion.usdoj.gov/pubs/brochures/drugabuser.htm and http://www.deadiversion.usdoj.gov/pubs/pressrel/dr_scam.htm.

6. Federal Policy

Existing DEA policy recognizing the use of opioids for chronic pain should be disseminated more widely in the medical, pharmacy, and nursing communities.

Progress. The DEA regulations for prescribing and dispensing controlled substances are available on the following websites: DEA Diversion Control Program (http://www.deadiversion.usdoj.gov/21cfr/cfr/2106cfrt.htm), Government Printing Office (http://www.access.gpo.gov/nara/cfr/waisidx_00/21cfr1306_00.html), and by link from PPSG (http://www.medsch.wisc.edu/painpolicy). A DEA statement on the use of controlled substances for pain management is being drafted. It will be included in revisions of existing DEA publications about controlled substances for physicians,[15] pharmacists,[41] and nurses,[42] and will be included on its website: http://www.deadiversion.usdoj.gov/pubs/manuals/index.html. PPSG presentations generally include information about federal policy and informational resources.

7. Data

In keeping with state regulations, data from PMPs should be available to researchers to evaluate current trends in prescribing and the effectiveness of educational programs.

Progress. Data from prescription monitoring programs are available in the publications listed in item 1. Other projects that make use of PMP data, including university-sponsored research, are underway in various states. Educational facilities, pain management groups, and other specialty groups may find PMP data useful in evaluating treatment trends and the effectiveness of educational programs on pain management.

Conclusion

Representatives from pain management and prescription monitoring groups have recognized the importance of information exchange and cooperation. Since the meetings began in 1998, these groups have taken several important steps to increase cooperation and understanding and to nurture a mutual respect for the goals of each discipline. With continued activity expected in the states to improve pain management and address drug diversion, it is essential to continue these efforts to provide accurate information and promote communication and understanding between the groups involved.

Providing adequate pain management and preventing diversion and abuse of prescription controlled substances are both important public health goals. Achieving both goals requires exchange of information and perspectives, identification of issues, and concerted action. Increased communication and cooperation between regulatory and pain groups can contribute to a good balance between drug control and drug availability.

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References

1. Wolfe J, Grier HE, Klar N, et al. Symptoms and suffering at the end of life in children with cancer. N Engl J Med 2000;342(5):326–333.

2. Bernabei R, Gambassi G, Lapane K, et al. Management of pain in elderly patients with cancer. JAMA 1998;279(23):1877–1882.

3. Cleeland CS, Gonin R, Baez L, et al. Pain and treatment of pain in minority patients with cancer. Ann Intern Med 1997;127:813–816.

4. Institute of Medicine Committee on Care at the End of Life. Approaching death: improving care at the end of life. Washington, DC: National Academy Press, 1997.

5. SUPPORT Study Principal Investigators. A controlled trial to improve care for seriously ill hospitalized patients: the Study to Understand Prognoses and Preferences for Outcomes and Risks of Treatments (SUPPORT). JAMA 1995;274(20):1591–1598.

6. Jacox A, Carr DB, Payne R, et al. Management of cancer pain. In: Clinical Practice Guideline Number 9. Rockville, MD: Agency for Health Care Policy and Research. U.S. Dept of Health and Human Services, Public Health Service, 1994. AHCPR publication 94-0592.

7. Cleeland CS, Gonin R, Hatfield AK, et al. Pain and its treatment in outpatients with metastatic cancer. N Engl J Med 1994;330(9):592–596.

8. American Pain Society. Principles of analgesic use in the treatment of acute pain and cancer pain, 4th ed. Glenview, IL: American Pain Society, 1999.

9. Acute Pain Management Guideline Panel. Acute pain management: operative or medical procedures and trauma. In: Clinical practice guideline. Rockville, MD: Agency for Health Care Policy and Research, U.S. Dept of Health and Human Services, Public Health Service, 1992. AHCPR publication 92-0032.

10. Portenoy RK. Opioid therapy for chronic nonmalignant pain: clinician's perspective. J Law Med Ethics 1996;24(4):296–309.

11. World Health Organization. Cancer pain relief. Geneva, Switzerland: World Health Organization, 1986.

12. Levy MH. Pharmacologic treatment of cancer pain. N Engl J Med 1996;335:1124–1132.

13. Doyle D, Hanks G, MacDonald N. Oxford textbook of palliative medicine. New York: Oxford University Press, 1993.

14. Pappagallo M, Heinberg LJ. Ethical issues in the management of chronic nonmalignant pain. Semin Neurol 1997;17:203–211.

15. Drug Enforcement Administration. Physician's manual: an informational outline of the Controlled Substances Act of 1970. Washington, DC: U.S. Department of Justice, 1990.

16. Controlled Substances Act of 1970. Pub L. No. 91-513, 84 Stat 1242.

17. National Conference of Commissioners on Uniform State Laws. Uniform Controlled Substances Act. NCCUSL: Chicago, IL. Adopted at its Annual Conference Meeting in its One-Hundred-and-Third-Year; Chicago, IL; 29 July–5 August 1994.

18. American Medical Association. Curtailing prescription drug abuse while preserving therapeutic use: American Medical Association recommendations for drug control policy. In: Wilford BB, ed. Bal-

ancing the response to prescription drug abuse. Chicago: American Medical Association; 1990:273–298.

19. New York State Public Health Council. Breaking down the barriers to effective pain management: recommendations to improve the assessment and treatment of pain in New York State. Albany, NY: New York State Department of Health, 1998.

20. Alliance of States with Prescription Monitoring Programs. The goals of prescription monitoring. Jamaica Plain, MA: Massachusetts Department of Health. Drug Control Program, 1999. (Can be accessed at http://www.nascsa.org/monitoring.htm)

21. Drug Enforcement Administration, National Alliance for Model State Drug Laws. Diversion and abuse of prescription drugs: A closer look at state prescription monitoring programs. Washington, DC: Drug Enforcement Administration, 2000. (Can be accessed at http://www.deadiversion.usdoj.gov/pubs/program/rx_monitor/index.html)

22. Joranson DE, Ryan KM, Gilson AM, Dahl JL. Trends in medical use and abuse of opioid analgesics. JAMA, 2000;283(13):1710–1714.

23. National Association of State Controlled Substances Authorities. Model prescription accountability act. Colonial Williamsburg, VA; 2 November 1996: National Association of State Controlled Substances Authorities. (Can be accessed at http://www.nascsa.org/monitoring.htm)

24. Drug Enforcement Administration—Office of Diversion Control. Prescription accountability resource guide. Washington, DC: Drug Enforcement Administration, 1998. (Can be accessed at http://www.deadiversion.usdoj.gov/pubs/program/rx_account/index.html)

25. Joranson DE, Gilson AM, Ryan KM, et al. Achieving balance in federal and state pain policy: A guide to evaluation. Madison, Wisconsin: Pain & Policy Studies Group, University of Wisconsin Comprehensive Cancer Center, 2000. (Can be accessed at http://www.medsch.wisc.edu/painpolicy/cguide2000/index.html)

26. National Association of State Controlled Substances Authorities. NASCSA Resolution 99-01. A resolution endorsing the Model Guidelines for the Use of Controlled Substances for the Treatment of Pain. Adopted at the NASCSA 15th Annual Educational Conference; Coeur d'Alene, Idaho; 29 October 1999. (Can be accessed at http://www.nascsa. org/resolutions/res9901.htm)

27. Weissman DE, Haddox JD. Opioid pseudoaddiction—an iatrogenic syndrome. Pain 1989;36:363–366.

28. Drug Enforcement Administration—Office of Diversion Control. Committee report on establishing a state prescription monitoring program. Washington, DC: Drug Enforcement Administration. 1995.

29. Sigler KA, Guernsey BG, Ingrim NB, et al. Effect of a triplicate prescription law on prescribing of Schedule II drugs. Am J Hosp Pharm 1984;41:108–111.

30. Berina LF, Guernsey BG, Hokanson JA, et al. Physician perception of a triplicate prescription law. Am J Hosp Pharm 1985;42:857–859.

31. Weintraub M, Singh S, Byrne L, Maharaj K, Guttmacher L. Consequences of the 1989 New York State Triplicate Benzodiazepine Prescription Regulations. JAMA 1991;266:2392–2397.

32. Wastila LJ, Bishop C. The influence of multiple copy prescription programs on analgesic utilization. J Pharm Care Pain Symptom Control 1996;4(3):3–19.

33. Cooper JR, Czechowicz DJ, Molinari SP, Petersen RC. Impact of prescription drug diversion control systems on medical practice and patient care. NIDA Research Monograph 131. Rockville, MD: National Institute on Drug Abuse, 1993.

34. Indiana Board of Pharmacy. Report of the Indiana Board of Pharmacy to the legislative council concerning the electronic monitoring of controlled substances. Indianapolis: Indiana Board of Pharmacy, 1997.

35. Michigan Department of Commerce, Michigan Controlled Substances Advisory Commission. Michigan triplicate prescription program: evaluation report. East Lansing: Michigan Department of Commerce, 1993.

36. Michigan Department of Consumer & Industry Services, Michigan Controlled Substances Advisory Commission. Michigan official prescription program: evaluation report. East Lansing: Michigan Department of Consumer & Industry Services, 1997.

37. New York State Department of Health. Benzodiazepines: additional effects of the triplicate program. NYS J Med 1990;90:273–275.

38. New York State Department of Health. Benzodiazepines: prescribing declines under triplicate program. NYS J Med 1990;90:218–220.

39. Institute of Medicine Committee on Opportunities in Drug Abuse Research. Pathways of addiction: opportunities in drug abuse research. Washington, DC: National Academy Press, 1996.

40. Federation of State Medical Boards of the United States Inc. Model guidelines for the use of controlled substances for the treatment of pain. Euless, TX: Federation of State Medical Boards of the United States Inc, 1998. (Can be accessed under "Policy Documents" at http://www.fsmb.org)

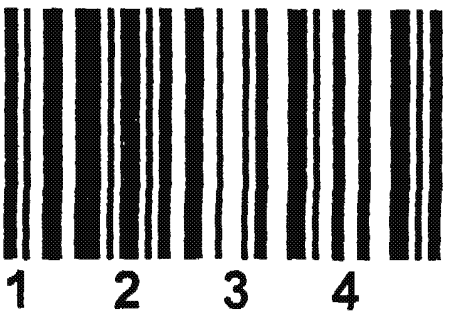
41. Drug Enforcement Administration. Pharmacist's manual: an informational outline of the Controlled Substances Act of 1970. Washington, DC: US Department of Justice, 2001. (Can be accessed at http://www.deadiversion.usdoj.gov/pubs/manuals/pharm2/index.htm).

42. Drug Enforcement Administration. Mid-level practitioner's manual: an informational outline of the Controlled Substances Act of 1970. Washington, DC: US Department of Justice, 1993.

SECTION

13

RELATED REPORTS AND DOCUMENTS



Targeted End-of-Life Projects Initiative
"Building Capacity to Promote Pain Policy Through
Evaluation, Research and Communication"
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PPSG I
PPSG U

U.S. Senate Hearing on Pain Management and Improving End of Life Care

October 13, 1999

Testimony of
David E. Joranson
University of Wisconsin Pain & Policy Studies Group
http://www.medsch.wisc.edu/painpolicy

My name is David E. Joranson. I am a Senior Scientist and Director of the Pain & Policy Studies Group, University of Wisconsin Comprehensive Cancer Center, Madison. I thank the Committee on Health, Education, Labor and Pensions for the opportunity to address the Committee.

I applaud the Committee for taking an interest in what you can do to improve pain management and end of life care in the United States; this is of course the ultimate matter of quality of life for us all. I encourage the Committee to take time to develop a full perspective on the human, medical, social and policy aspects, to become familiar with the unique barriers, assess what is already being done, and then consider the options. I can contribute to one part of your picture; my area of knowledge is controlled substances policy and the regulation of medical practice in relation to pain management.

The Committee has before it two pieces of legislation to improve pain management: One is S. 941, to amend the Public Health Service Act, the other is S. 1272, to amend the Controlled Substances Act (CSA). My comments will focus on the risks that should be considered before amending the CSA as has been proposed.

It is important to realize that the CSA has a dual purpose relating to both drug abuse prevention and also to recognizing and preserving the important medical uses of many controlled substances. Indeed, achieving a 'balanced' drug control policy is an obligation of governments which is established by the United Nations Single Convention on Narcotic Drugs, 1961, i.e., to prevent the misuse of drugs without interfering with their medical use, in particular for the relief of pain and suffering. The CSA was structured by the Congress to achieve a balance between these two purposes. When controlled substances policy loses its balance, the chances increase for there to be conflict between law enforcement and medicine, with resulting harm to pain management and patient care.

The CSA is a law enforcement statute aimed at preventing abuse of controlled substances, and for these purposes it is administered by the Attorney General (AG). The CSA also recognizes that many controlled substances (such as opioid analgesics) are necessary to maintain public health, and that they must be available to meet legitimate medical and scientific needs.

In order to achieve this balance, the Congress spelled out several fundamental principles which recognize that certain functions are to be carried out under jurisdictions other than federal drug law enforcement in the Department of Justice. These three areas are: (1) the medical and scientific decisions necessary to administer the CSA, (2) the recognition of the medical uses of drugs, and (3) the recognition of the role of State laws, especially those regulating medical practice.

(1) Medical and scientific decisions. The Congress decided in 1970 that medical and scientific decisions,

such as the evaluation of the potential for abuse of drugs being placed in the five schedules of the CSA, are the responsibility of the Secretary of the Department of Health and Human Services (DHHS), not the AG (See Section 811.(b) of the CSA). The principle of "balance," was established in the course of vigorous and extended debate over a Department of Justice bill that, as proposed, would have given the AG exclusive power to make decisions of a medical and scientific nature. Congress appropriately rejected this approach and assigned this authority to the DHHS. Medical and scientific organizations were actively involved to ensure that the CSA was balanced in this respect, and this policy has endured to this day, including amendments to the CSA which were adopted in 1984 to increase DEA's capability to revoke practitioner registrations in the public interest.

(2) Relation of the CSA to the Federal Food, Drug and Cosmetic Act. The Congress determined a second fundamental principle, that the CSA is not to "be construed as in any way affecting...the provisions of the Federal Food, Drug and Cosmetic Act" (See Section 902). It is extremely important to recognize that it is under authority of the FFDCA, not the CSA, that drugs are approved as safe and effective for medical use, so that they can be marketed lawfully in interstate commerce. In addition, federal administrative law and court decisions have made it clear that although the Food and Drug Administration (FDA) approves drugs for marketing, it does not regulate medical practice, which is left to the States. Many opioid analgesics have been approved for treatment of pain, and also for diarrhea, and cough. The fact that opioids (and many other drugs approved for human use under the FFDCA) are *also* controlled substances under the CSA is not intended to affect their status as drugs which are safe and effective and may be prescribed by physicians. Indeed, the difference between legal and illegal drugs in the schedules of the CSA is defined by whether a drug is approved under the FFDCA as having an accepted medical use.

(3) Relation of the CSA to State laws. The third principle reflects the fundamental relation between the federal government and the States. The CSA is not intended to occupy areas of State laws which are within the authority of the States:

> "No provision of this subchapter shall be construed as indicating an intent on the part of the Congress to occupy the field in which that provision operates, including criminal penalties, to the exclusion of any State law on the same subject matter which would otherwise be within the authority of the State, unless there is a positive conflict between that provision of this subchapter and that State law so that the two cannot consistently stand together." (CSA, Section 903).

It would be extraordinary to invoke the federal CSA to contravene the policy of a single state, or to use the CSA to establish medical and scientific policy with respect to drugs.

Mr. Chairman, against the context of the foregoing fundamental principles which limit the scope of the CSA, I offer a few concluding observations:

(1) Opioid analgesics are already legal. This is determined under the FFDCA. To define or comment on the medical uses in a federal drug law enforcement statute ignores one of the fundamental principles of balance.

(2) The DEA has already said that they understand that opioid analgesics are needed for chronic pain. A 1974 DEA regulation made it perfectly clear that nothing in the CSA precludes practitioners from providing opioids for intractable pain. DEA reemphasized this point again in its 1990 Physicians Manual, encouraging physicians to prescribe opioids when they are needed:

> "Controlled substances and, in particular, narcotic analgesics, may be used in the treatment of pain experienced by a patient with a terminal illness or chronic

> disorder. These drugs have a legitimate clinical use and the physician should not hesitate to prescribe, dispense or administer them when they are indicated for a legitimate medical purpose. It is the position of the Drug Enforcement Administration that these controlled substances should be prescribed, dispensed or administered when there is a legitimate medical need." (DEA, 1990, p. 21)

Indeed, DEA representatives are to be commended for their willingness to clarify federal policy in relation to medical practice; they have spoken at numerous pain conferences around the U.S. The DEA, and major medical organizations, have endorsed a new Model Guideline on the use of controlled substances for pain.

(3) New DEA regulations? S. 1272 contemplates that the AG/DEA may promulgate "regulations to implement this Act." Is it appropriate to give DEA rule-making authority in this sensitive area? How will the agency distinguish between pain management and assisted suicide? Apart from the inherent difficulty in determining a physician's intention, a recent review supported the notion that opioids hasten death is more myth than fact. Given that H.R. 2260 allows for DEA regulations in connection with new language about pain, hastening death and assisted suicide, it seems likely that the Attorney General and the DEA would be faced with decisions which involve medicine and science, conflicting with the first fundamental principle.

(4) The potential for a chilling effect. I will close with the following point. I assume that this Committee fully accepts that pain is not adequately managed in this country, and that this is due, in part, to the under-use of opioid analgesics, especially, but not only, for people at the end of life. One of the reasons is that while many physicians still do not have sufficient knowledge about pain management, they also fear being investigated if they prescribe 'too much.' The origin of these fears goes back many years, and are in part an unintended effect of the war on drugs. The solution to this problem requires that we give greater attention to achieving a balanced controlled substances policy which clearly recognizes that controlled substances have important medical uses, and that we communicate it so that it is understood by regulators and practitioners. The amendments to the CSA which have been proposed threaten to upset the balance that the Congress has established, and which many of us have been working to achieve. When balance in controlled substances policy is upset, the chances for conflict between law enforcement and medicine increase, as does the likelihood that patient care will be harmed.

I will mention some of the organizations that have recognized that the barriers to pain management include physicians' concern about regulation of controlled substances, particularly at the state level:

> The American Academy of Pain Medicine
> The American Medical Association
> The American Pain Society
> The Cancer Pain Clinical Practice Guideline Panel of the U.S. Agency for Health Care Policy and Research
> The Federation of State Medical Boards of the U.S.
> The Medical Board of California
> The National Academy of Sciences, Institute of Medicine
> The National Conference of Commissioners on Uniform State Laws
> The National Conference of State Legislatures
> The State Cancer Pain Initiatives

Both pieces of legislation would establish education and training programs about pain management and palliative care which would be valuable, especially if directed to policy makers, and law enforcement and regulatory personnel. Indeed, our Group has conducted eleven workshops on "pain management in a regulated environment" for state medical board members, with support from the Robert Wood Johnson

Foundation.

Mr. Chairman, I thank the Committee for this opportunity to testify. In sum, I ask you to evaluate carefully any proposed amendments to the federal CSA to determine if they support or conflict with the principles which make the CSA a "balanced" act. I would urge the Committee to pursue other measures that could more directly address the root causes of inadequate pain management, for all stages of life, without disturbing the sensitive balance that is needed in controlled substances policy. I am happy to take questions or provide further information.

Note: Pursuant to the Committee's instructions to witnesses, I do not have and have not received any federal grants, and I am not representing any other party at this hearing.

Selected Bibliography

Alpers A. Criminal act or palliative care? Prosecutions involving the care of the dying. *The Journal of Law, Medicine & Ethics*. 1998; 26:308-331.

Fohr SA. The double effect of pain medication: Separating myth from reality. *The Journal of Palliative Medicine*. 1998;1(4):315-328.

Joranson DE. Federal and state regulation of opioids. *Journal of Pain and Symptom Management.* 1990;5(Suppl):12-23.

Joranson DE. A new drug law for the states: An opportunity to affirm the role of opioids in cancer pain relief. *Journal of Pain and Symptom Management,* 1990;5(5):333-336.

Joranson DE, Gilson AM. Controlled substances, medical practice, and the law. In: Schwartz HI, ed. *Psychiatric Practice Under Fire: The Influence of Government, the Media, and Special Interests on Somatic Therapies*. Washington, DC: American Psychiatric Press, 1994:173-194.

Joranson DE, Gilson AM. Improving pain management through policy making and education for medical regulators. *The Journal of Law, Medicine & Ethics*. 1996;24(4):344-347.

Joranson DE, Gilson AM. Controlled substances and pain management: A new focus for state medical boards, *Federation Bulletin: The Journal of Medical Licensure and Discipline*. 1998;85(2):78-83.

Martino AM. In search of a new ethic for treating patients with chronic pain: What can medical boards do? *The Journal of Law, Medicine & Ethics*. 1998;26:332-349.

Musto DF. *The American Disease: Origins of Narcotic Control*. 3rd ed. New York, NY: Oxford University Press, 1999.

Von Roenn JH, Cleeland CS, Gonin R, Hatfield AK, Pandya KJ. Physician attitudes and practice in cancer pain management: A survey from the Eastern Cooperative Oncology Group. *Annals of Internal Medicine*. 1993;119:121-126.

Weissman DE. Doctors, opioids, and the law: The effect of controlled substances regulations on cancer pain management. *Seminars in Oncology*. 1993;20(2 Suppl 1):53-58.

[1] My knowledge and experience with controlled substances law goes back about thirty years, to the vigorous debate and final adoption in 1970 of the CSA. In addition I have had the following relevant experiences: administrative officer for the State of Wisconsin's Controlled Substances Board; worked with Congressional subcommittees to successfully adopt amendments to the CSA in 1984 to strengthen DEA's program against diversion of controlled substances; co-founded the National Association of State Controlled Substances Authorities and the first State Cancer Pain Initiative, which became a World Health Organization Demonstration Project; conducted research on Federal and state controlled substances laws and state professional practice laws and regulations; served for several years on the drafting committee of the National Conference of Commissioners on Uniform State Laws to revise the Uniform Controlled Substances Act for the States; assisted in the development of state medical board guidelines for the use of controlled substances in the treatment of pain; worked with the National Conference of State Legislatures to develop informational materials for state legislatures.

[2] "Controlled Dangerous Substances, Narcotic and Drug Control Laws" Hearings before the U.S. House of Representatives Committee on Ways and Means. Washington, DC: U.S. Government Printing Office, 1970.

[3] Code of Federal Regulations Part 21, Section 1306.07(c)

[4] Drug Enforcement Administration. *Physician's Manual: An Informational Outline of the Controlled Substances Act of 1970*. U.S. Department of Justice: DEA; March, 1990.

[5] Federation of State Medical Boards of the United States, Inc. *Model Guidelines for the Use of Controlled Substances for the Treatment of Pain*. Euless, TX; May 1998.

[6] Fohr SA. The double effect of pain medication: Separating myth from reality. *Journal of Palliative Medicine*. 1998;1(4):315-328.

Targeted End-of-Life Projects Initiative
"Building Capacity to Promote Pain Policy Through Evaluation, Research and Communication"
Grant # 036509

About the PPSG

JAMA Article

Policy Alert

Law:

US Pain Policies

Matrix of Statutes, Regulations, & Guidelines

Testimony

International

WHO Newsletter *"Cancer Pain Release"*

Glossary

Bibliography

Feedback

Links

Search

Quick Reference

Evaluation Guide of 17 States

Federal Pain Regulations

Model Guidelines

Pain & Policy Studies Group

University of Wisconsin Comprehensive Cancer Center

World Health Organization Collaborating Center for Policy and Communications in Cancer Care

"Studying public policy in relation to pain management"

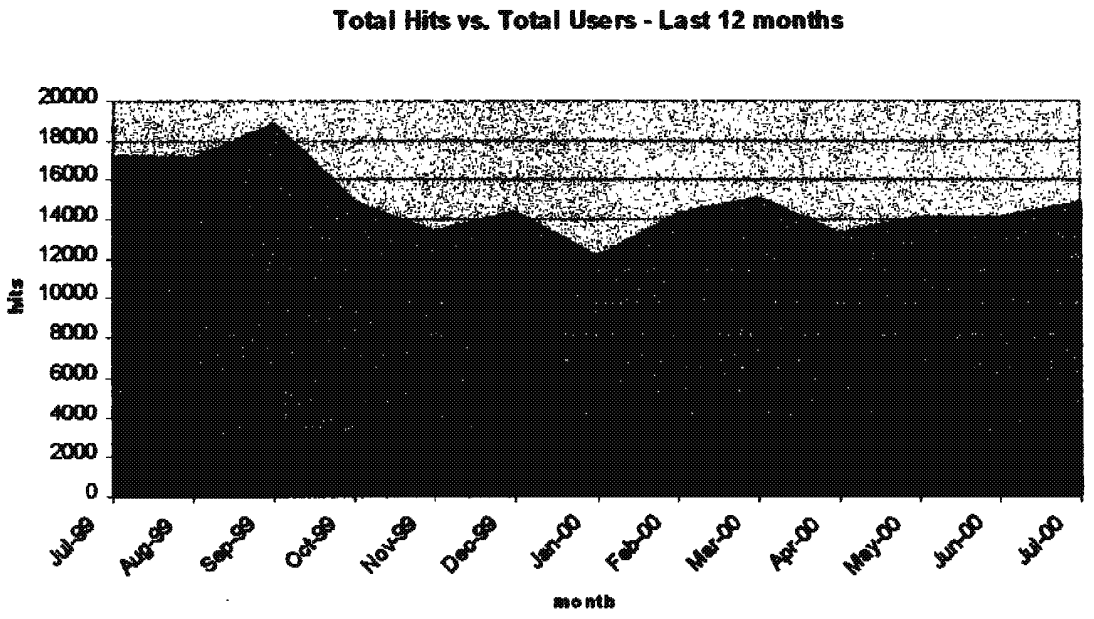
The purpose of this website is to facilitate public access to information about pain relief and public policy, including material published by the PPSG and other authoritative sources.

The **intended audiences** for this information include patients, the public, and professionals in medicine, pharmacy, nursing, palliative care, cancer care, law, and other related disciplines. The Pain & Policy Studies Group, at the University of Wisconsin, addresses both domestic and international policy issues and is a World Health Organization Collaborating Center for Policy and Communications in Cancer Care.

If you are new to the area of pain and policy studies, **start with** our selected readings, and our Resource Guide.

Pain & Policy Studies Group
1900 University Avenue
Madison, WI 53705-4013
Phone: (608)263-7662
Email: ppsg@med.wisc.edu

Web Server Statistics for the PPSG Website for July



I. Cumulative total: 338,476

II. July 2000

Number of hits:	14,906
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"Top page" hits

1996 PPSG report	83
About the PPSG	83
Alerts	92
Bibliography	140
Front page	1435
Glossary	102
Links	127
Related Reading	127
Selected Reading	262
U.S. page	334
Evaluation Guide	218
States Pain Policy	334
Matrix	313
JAMA	256

International hits: Australia (56), Canada (114), Germany (23), Israel (7), Brazil (5), United Kingdom (61), Italy (14), Belgium (7), France (5), Argentina (8), Japan (26), New Zealand (20), Mexico, Singapore (5), Switzerland (4), Norway, Czech Republic (1), Sweden (7), Saudi Arabia, India (2), Chile, Peru (1), Finland, Greece (2), Netherlands (17), Philippines (1), Thailand (1), Uruguay, Kenya, Ireland (2), Portugal (1), Poland (2), Hong Kong (1), Malaysia (12), Iceland, Slovenia (1), Spain (5), Colombia (6), Taiwan, Estonia, Luxembourg, Hungary, South Africa (4), Denmark (2), Bermuda

Top Article Hits for July

355	Current Thoughts on Opioid Analgesics
294	Controlled Substances, Medical Practice...
285	Is Methadone Maintenance the Last Resort...?
181	Opioids for Chronic Cancer and Non-cancer Pain
173	State Intractable Pain Policy: Current Status
169	Responding to Prescription Drug Abuse
168	Federal and State Regulation of Opioids
156	State Controlled Substances Laws and Pain...
125	Cancer Pain Relief, with a Guide to Opioid...
88	Intractable Pain Treatment Laws and Regulations
84	Asia Monograph
79	Recent Developments in Pain Management...
76	State Medical Board Guidelines for Intractable Pain...
66	Off-label Uses of Prescription Drugs in Pain...
59	Latin American Monograph

Top State Pain Policy Hits for July

847	Resource Guide
377	Model Guidelines
73	Arkansas MB Regulation
62	Texas Law
59	Tennessee MB
58	California Law
57	Mississippi MB Statement
56	California MB
53	Massachusetts MB
47	Ohio MB
47	Barriers (from AHCPR)
46	Louisiana MB Regulation
43	North Carolina MB

INDEX FOR THE PPSG WEBSITE

- About the PPSG
- JAMA article: "Trends in the Use and Abuse and Abuse of Opioid Analgesics"
- Policy Alert: Up-to-date information on current pain policy issues

Includes links to the following documents:

1. David Joranson's U.S. Senate Hearing Testimony (date posted: October 13, 1999)
2. David Joranson's Testimony on HR2260 (date posted: July 15, 1999)
3. Resource Guide - Information about Regulatory Issues in Pain Management (date posted: July 29, 1998)
4. Model Guidelines for the Use of Controlled Substances for the Treatment of Pain (date posted: July 29, 1998)
5. "What can state legislators do to improve pain management?" (date posted: January 16, 1998)
6. "Is methadone maintenance the last resort for some chronic pain patients?" (date posted: November 3, 1997)
7. Intractable Pain Treatment Acts (date posted: July 27, 1997)

LAW:

- U.S. Pain Policies

1. Introductory Note
2. Matrix of State Laws, Regulations, and Guidelines (see Matrix of State Laws, Regulations, and Guidelines below)
3. 17 State Evaluation Guide - "Achieving Balance in State Pain Policy," July 1999, which is a document that presents a framework for understanding the potential of existing policies to enhance or impede pain management.(will be replaced by the complete Guide to all 50 states and federal policy during the next year of the grant)
4. State Cancer Pain Initiatives Contact List - American Alliance of Cancer Pain Initiatives
5. Resource Guide, July 1998 - Information about regulatory issues in pain management
6. Published literature on pain policy

Includes links to the following articles:

<u>Chronic Pain Treatment Policy</u>

1994 Controlled substances, medical practice, and the law
1995 Intractable pain treatment laws and regulations
1997 State Intractable Pain Policy: Current Status
1997 The Use of Opioids for the Treatment of Chronic Pain

<u>Controlled Substances Policy</u>

1990 Federal and state regulation of opioids
1990 A new drug law for the states
1992 State controlled substances laws and pain control
1992 Pain and euthanasia: the need for alternatives.
1993 Guiding principles of international and federal laws pertaining

to medical use and diversion of controlled substances
1993 Wins and losses in pain control
1994 Controlled substances, medical practice, and the law
1997 Is methadone maintenance the last resort for some chronic pain patients?

Food and Drug Policy

1990 Federal and state regulation of opioids
1994 Controlled substances, medical practice, and the law
1995 Off-label uses of prescription drugs in pain management

Reimbursement Policy

1994 Healthcare Reimbursement Policies: Do they block acute and cancer pain management?
1994 Are health care reimbursement policies a barrier to acute and cancer pain management?

State Medical Board Policy

1994 Recent developments in pain management and regulation
1995 State medical board guidelines for intractable pain treatment
1996 Improving pain management through policy making and education for medical regulators
1997 State intractable pain policy: current status

Prescription Drug Abuse, Diversion, and Monitoring Programs

1992 Single-copy serialized prescriptions: old regulation in new clothing?
1993 Wins and losses in pain control
1993 More federal drug control initiatives: Are they warranted? Will they consider the patient?
1994 Controlled substances, medical practice, and the law
1994 Policy issues and imperatives in the use of opioids to treat pain in substance abusers

Concern About Regulatory Scrutiny

1991 Wisconsin physicians' knowledge and attitudes about opioid analgesic regulations
1992 Opioids for chronic cancer and non-cancer pain: a survey of state medical board members
1992 Legislating proper pain management

1994 Recent developments in pain management and regulation
1994 Controlled substances, medical practice, and the law
1996 Improving pain management through policy making and education for medical regulators

Concern About Addiction

1994 Policy issues and imperatives in the use of opioids to treat pain in substance abusers
1994 Controlled substances, medical practice, and the law
1995 Current thoughts on opioid analgesics and addiction

Pain Commissions/Summits

1994 California sponsors pain summit; Maryland fends off new regulations

Assisted Suicide and Pain

1992 Pain and euthanasia: the need for alternatives

Wisconsin Cancer Pain Initiative

1988 A report of the Wisconsin Cancer Pain Initiative
1990 The Wisconsin Cancer Pain Initiative
1991 Wisconsin physicians' knowledge and attitudes about opioid analgesic regulations

7. FAQ's - Frequently Asked Questions
   This page provides the answers to the following FAQs:
   1. What can state legislatures do to improve pain management?

• Matrix of State Laws, Regulations, and Guidelines
  Includes links to the following policies:

1. Federation of State Medical Boards: "Model Guidelines for the Use of Controlled Substances for the Treatment of Pain"
2. National Association of State Controlled Substances Authorities: "Resolution Endorsing Federation's Model Guidelines"
3. Alabama Medical Board Regulation
4. Arizona Medical Board Guideline
5. Arkansas Medical Board Regulation
6. California Intractable Pain Treatment Act
7. California Pain Patient's Bill of Rights

8. California Medical Board Guideline
9. California Medical Board Policy Statement
10. Colorado Statute
11. Colorado Intractable Pain Treatment Act
12. Colorado Medical Board Guideline
13. Florida Statute
14. Florida Medical Board Regulation
15. Georgia Medical Board Guideline
16. Idaho Medical Board Guideline
17. Iowa Medical Board Regulation
18. Kansas Medical Board Guideline
19. Kentucky Medical Board Guideline
20. Louisiana Medical Board Regulation
21. Maine Medical Board Regulation
22. Maryland Medical Board Guideline
23. Massachusetts Medical Board Guideline
24. Michigan Statute
25. Minnesota Intractable Pain Treatment Act
26. Mississippi Medical Board Regulation
27. Mississippi Medical Board Policy Statement
28. Missouri Intractable Pain Treatment Act
29. Montana Medical Board Guideline
30. Nebraska Statute
31. Nebraska Medical Board Guideline
32. Nevada Statute
33. Nevada Medical Board Regulation
34. Nevada Medical Board Regulation
35. New Hampshire Statute
36. New Hampshire Medical Board Guideline
37. New Jersey Regulation
38. New Jersey Medical Board Regulation
39. New Mexico Statute
40. New Mexico Medical Board Guideline
41. North Carolina Medical Board Policy Statement
42. North Carolina Medical Board Policy Statement
43. North Carolina Joint Policy Statement
44. North Dakota Intractable Pain Treatment Act
45. Ohio Intractable Pain Treatment Act
46. Ohio Medical Board Regulation
47. Ohio Medical Board Policy Statement
48. Oklahoma Statute
49. Oklahoma Medical Board Regulation
50. Oregon Intractable Pain Treatment Act
51. Oregon Medical Board Regulation
52. Oregon Medical Board Policy Statement

53. Pennsylvania Medical Board Guideline
54. Rhode Island Intractable Pain Treatment Act
55. Rhode Island Medical Board Guideline
56. South Carolina Medical Board Guideline
57. Tennessee Medical Board Regulation
58. Tennessee Medical Board Policy Statement
59. Texas Intractable Pain Treatment Act
60. Texas Medical Board Regulation
61. Texas Medical Board Policy Statement
62. Utah Medical Board Guideline
63. Vermont Medical Board Guideline
64. Virginia Statute
65. Virginia Medical Board Guideline
66. Washington Statute
67. Washington Medical Board Regulation
68. Washington Medical Board Guideline
69. West Virginia Intractable Pain Treatment Act
70. West Virginia Medical Board Policy Statement
71. Wisconsin Statute
72. Wyoming Medical Board Policy Statement

• Testimony - link to David Joranson's Testimony

David Joranson's U.S. Senate Hearing Testimony - October 13, 1999
David Joranson's Testimony on HR2260 - June 24, 1999

• International

Includes links to the following sections relating to international pain policy:

1. World Health Organization Publications
2. Latin America: Opioid Analgesics for Cancer Pain Relief: A Review of Consumption Trends and the Literature
3. Asia: Opioid Analgesics for Cancer Pain Relief: A review of Consumption Trends and the Literature
4. Europe: Opioid Availability: Diagnosis and Treatment of Regulatory Barriers
5. General: To what extent has the WHO Analgesic Ladder influenced morphine consumption in the world?

• WHO Newsletter "Cancer Pain Release"

• Glossary

Includes definitions for the following terms:

- Addiction
- Guideline
- Law (Statutes and Regulations)
- Narcotic

- Opiate
- Opioid
- Schedules of controlled substance
- Tolerance
- Physical dependence
- Psychological dependence

• Bibliography

Includes links to the following articles:

United States

1. Controlled Substances and Pain Management: A New Focus for State Medical Boards
2. 1998 Resource Guide - Information about Regulatory Issues in Pain Management
3. Is methadone maintenance the last resort for some chronic pain patients?
4. State intractable pain policy: current status
5. The Use of Opioids for the Treatment of Chronic Pain
6. Improving pain management through policy making and education for medical regulators
7. State pain commissions: new vehicles for progress?
8. State medical board guidelines for intractable pain treatment
9. Intractable pain treatment laws and regulations
10. Off-label uses of prescription drugs in pain management
11. Policy issues and imperatives in the use of opioids to treat pain in substance abusers
12. Are health care reimbursement policies a barrier to acute and cancer pain management?
13. Controlled substances, medical practice and the law
14. Healthcare reimbursement policies: Do they block acute and cancer pain management?
15. California sponsors pain summit; Maryland fends off new regulations
16. Recent developments in pain management and regulation
17. Guiding principles of international and federal laws pertaining to medical use and diversion of controlled substances
18. Availability of opioids for cancer pain: recent trends, assessment of system barriers, new WHO guidelines, and the risk of diversion
19. Wins and losses in pain control
20. More federal drug control initiatives: Are they warranted? Will they consider the patient?
21. Regulatory influence on pain management: real or imagined?
22. Cancer pain: the U.S. responds
23. Opioids for chronic cancer and non-cancer pain: a survey of state medical board members
24. Single-copy serialized prescriptions: old regulation in new clothing?
25. State controlled substances laws and pain control
26. Pain and euthanasia: the need for alternatives
27. Legislating proper pain management
28. Cancer pain and regulation of opioids: balancing drug control and availability
29. Wisconsin physicians' knowledge and attitudes about opioid analgesic regulations
30. Federal and state regulation of opioids
31. A new drug law for the states: an opportunity to affirm the role of opioids in cancer pain relief

32. Oral morphine for the treatment of cancer pain
33. Why is a balanced policy important, and do we have it now?
34. The Wisconsin Cancer Pain Initiative
35. Achieving balance in drug policy: the Wisconsin model
36. The Wisconsin Cancer Pain Initiative: a progress report
37. Responding to prescription drug abuse
38. A report on the Wisconsin Cancer Pain Initiative
39. Wisconsin initiative for improving cancer pain management: progress reports
40. Delta 9 Tetrahydrocannabinol and therapeutic research legislation for cancer patients

• Feedback

• Links

Includes links to U.S. organizations that study pain policy:

American Academy of Pain Medicine
American Pain Foundation
American Pain Society
American Society of Addiction Medicine
American Society of Law, Medicine & Ethics
Cancer Detection & Prevention
End of Life Physician Education Resource Center
Federation of Medicine
The Joint Commission on Accreditation of Healthcare Organizations
Last Acts
National Association of Boards of Pharmacy
National Conference of State Legislatures
Pain Research Group
Project on Death In America
Robert Wood Johnson Foundation
University of Wisconsin
UW Comprehensive Cancer Center
Wisconsin Cancer Pain Initiative

• Search: Enables visitors to search our site by keyword or concept

• Quick Reference

1. Evaluation Guide of 17 States - "Achieving Balance in State Pain Policy," July 1999, which is a document that presents a framework for understanding the potential of existing policies to enhance or impede pain management. This page provides links to the Evaluation Guide in three different formats: (1) on-line interactive version, (2) text version, and (3) PDF version. The Evaluation Guide of 17 States will be replaced by the complete Guide to all 50 states and federal policy during the next year of the grant.

2. Federal Pain Regulations - Presents the section from the Code of Federal Regulations that relates to the prescribing of controlled substances.

3. Model Guidelines - Presents the full text of the Federation of State Medical Boards of the U.S.'s "Model Guidelines for the Use of Controlled Substances for the Treatment of Pain."

#3609 Central files

1/1 EOC

U of Wisconsin

Wood, Merry

From: David Joranson
Sent: Sunday, March 18, 2001 11:27 AM
To: MWOOD@rwjf.org
Cc: rgibson@rwjf.org; vdw@rwjf.org
Subject: status report

8/99 - 1/02

Dear Merry,

Here is the status report that you asked for..sorry it took so long but it took some time to organize the information and write it. Please note that it is not exhaustive. I hope it is what you were looking for. Please let me know your reactions and if you have questions. I'll copy Rosemary and Vicki on this too.

You-all might be interested in three other items, which I have not included in the report because of their sensitivity.

1. DEA is concerned about the sensational media coverage of oxycontin abuse and contacted my recently to discuss the possibility that we could organize a meeting of key pain organizations to meet with them to discuss the situation, explore various responses including a statement to the public and to medicine about the need for a balanced that takes into account the abuse potential of these drugs and also their important medical uses. I checked with key reps and everyone was very positive, so I am in the process of organizing a meeting of about 16 people including DEA (Pat Good), PPSG, APS (Underwood, Portenoy), AAPM (Jeff Engle), AACPI (June Dahl), C-SP (Myra) and Last Acts (Vicki, Karen).

2. We received a request from a lawyer to sign on to an *amicus* brief being submitted to the NM medical board which is in the process of disciplining a physician for inappropriate prescribing. We decided against it. But the interesting part was that the lawyer was making her case based on the NM Pain Relief Act (immunity if you follow accepted guidelines), and was dismayed that the board's attorney implied that the board basically ignored that law and any doc that counted on that law providing a shield or a 'safe harbor' was making a big mistake. My response to her was that the law essentially was a law school student project, and that the board had not supported the legislation, making the point that this is one reason why we avoid legislation to clarify policy and address physicians' fears of regulatory scrutiny, because if the board disagrees with the law they can undermine it. The metaphor was that there is a hostile warship in the 'safe harbor.' So here is a concrete example (with as much as we know about the situation) where safe harbor laws fail to achieve their goals. The hard work remains to change the attitude (or membership) of the board, and this was the same task that should have been addressed instead of introducing legislation.

3. I rec'd a call recently from a ID physician who lost his license for two years, from what I could make out, he was probably doing ok in taking care of 300 patients chronic non cancer and some cancer pts, except he admitted that his documentation was poor, but this was not the issue, the ID board policy statement says that use of opioids chronically requires consultation, he did not do that, and so the board nailed him for not obtaining cons. for pts with more than three months of opioids. (That requirement was

identified as an impediment in our eval guide) Now he has only a few days left to finish meeting with all his pts and helping them to find other docs, no small task in that rural area, and I expect some/most will have to cut down or eliminate their opioids, which will result in some big tragedies. I have been to Boise and have observed the board in action in a legislative hearing, and this is a board that definitely needs to be brought up to date.

Ideas welcome...

Best regards,

David

3/27/2001

Status Report

"Building Capacity to Promote Pain Policy Through Evaluation, Research and Communication"

In response to a request for a status report from the Robert Wood Johnson Foundation staff, PPSG staff have prepared the following report about its activities in 2000 and 2001 to date. Please note that the information is not exhaustive.

I. POLICY

The PPSG **has completed all of the policy projects of the first year of the grant. These include publication of the *Achieving Balance in Federal and State Pain Policies: A Guide to Evaluation* (the *Evaluation Guide*) and the *Annual Review of State Pain Policies, 2000* (the *Annual Review*).**

The *Evaluation Guide* is a 500-page document that presents the results of a systematic content evaluation of federal and state pain policies relating to controlled substances, medical and pharmacy practice. The document also contains recommendations for changing state policy, a discussion of the regulatory systems that affect pain management, and steps that legislatures and state agencies can take to improve pain management without interfering with medical practice. The purpose of the document is to promote a more "balanced" and consistent pain policy by improving knowledge about existing federal and state policy, resulting in a more positive policy environment for pain relief and end-of-life care.

The *Annual Review* is a 47-page document that summarizes and comments on each new or amended state statute, regulation and medical board policy affecting pain management that was adopted in the year 2000. It includes the full text of all the new policies and an appendix containing the Federation of State Medical Boards' "Model Guidelines for the Use of Controlled Substances for the Treatment of Pain." The policy activity in 2000 shows that while some boards are adopting balanced policies, others have not yet addressed this matter. There remains a large opportunity for state medical boards to adopt and communicate to licensees policies that encourage improved pain management.

PPSG has contacted all the state medical boards twice and pharmacy boards once to obtain all recently adopted and amended policies; these have been proofed and added to the electronic database of state pain policies on the PPSG website.

Several articles have been published and four more articles are in various stages of publication in major national peer-reviewed journals or books. These are listed in the sections on recent and pending publications.

In response to a question from Rosemary Gibson, PPSG provided a review of the North Carolina chronology of policy development and communication. Since 1994, the North Carolina Medical Board has adopted several policies, some in cooperation with the nursing board and pharmacy board, to recognize the use of controlled substances for pain management and end of life care. The Board has repeatedly communicated these activities to physicians through its newsletter, *Forum* and has sponsored educational programs aimed at health-care professionals and the public. The Board's efforts can serve as a model for medical boards in other states. PPSG plans to submit a brief report to the Federation Bulletin in an effort to spotlight this exemplary effort by the North Carolina boards.

II. COMMUNICATIONS

The following activities were aimed at getting the PPSG messages and products to the right audiences.

1. *Journal of the American Medical Association* article "Trends in Use and Abuse of Opioid Analgesics."

- JAMA developed and mailed a news release to 1500 reporters nationally. The news release was accessible to over 2,000 domestic and international journalists through "EurekAlert!" (a Web site for journalists maintained by the American Association for the Advancement of Science).

- PPSG developed and distributed a news release to 413 state medical societies, state medical boards, state boards of pharmacy, attorney generals, grant advisors, academic leaders and pain management advocates.

- PPSG sent an email notification with a link to the article to 166 academic leaders, pain management advocates, newsletters, professional societies and listserves.

- JAMA published our Letter to the Editor: In reply to "Reporting drug abuse in the Emergency Department" *JAMA* 284(5) in which PPSG praises the federal government for agreeing to make a number of improvements to the DAWN system that were recommended by PPSG in the article.

2. *Achieving Balance in Federal and State Pain Policy: A Guide to Evaluation*

- PPSG mailed 449 printed copies to state medical and pharmacy boards, state medical societies, grant advisors, academic leaders, pain management advocates and organizations, drug regulatory leaders, State Pain Initiatives, Community-State Partnerships, legislative librarians in all the states, as well as to select Members of Congress.

- PPSG sent an email notification with a link to the document on our website to a national list of 123 academic leaders, pain management advocates, newsletters, professional societies, list serves and to Wisconsin legislators.

- Requests continue to arrive; 85 additional Evaluation Guides have been distributed since the initial mailing.

3. *Annual Review of State Pain Policies 2000*

- PPSG sent 215 printed copies to the Cancer Pain Initiatives in the 5 states represented in the report, legislative librarians in all states, each state medical board and society, the National Advisory Committee for the Community-State Partnerships, and leaders in the pain field.

- PPSG sent an email notification with a link to the document on our website to a national list of 150 academic leaders, pain management advocates, newsletters, professional societies, Wisconsin legislators, and list serves.

4. *Journal of the American Pharmaceutical Association*, "Pharmacists' knowledge and attitudes about opioid pain medications in relation to federal and state policy." (In process)

- PPSG is sending an email notification to a national list of academic leaders, pain management advocates, pharmacy boards, leaders in Wisconsin pharmacy practice, and listserves. There will be a link to the abstract.

- PPSG organized a meeting with Wisconsin pharmacy leaders to give them a 'heads up' and to generate discussion about actions to address the deficiencies reported in the article. The Pharmacy Society of Wisconsin (PSW) plans to reprint the JAPhA article in their Journal which will be distrubuted to 3,000 practicing Wisconsin pharmacists. PSW is also considering a special mailing of the article and other pain management materials to all pharmacists. PSW has invited PPSG to present the results and recommendations to the PSW semi-annual and annual meetings. PSW is planning other related activities, such as a clinical commentary on the issues raised by the article, as well as an analysis of what pharmacists <u>can</u> do within the law, compared to what they usually hear about what they can't do.

5. Other communications activities have spotlighted PPSG work.

- The American Pain Foundation requested PPSG to write an article for their new newsletter, the *Pain Connection*. The article summarizes recent PPSG activities in the United States and abroad. It will be published in the spring of 2001.

- The National Council of State Legislatures requested PPSG to prepare a piece about its recent products that could be published November 6, 2000.

6. PPSG Brochure

- A brochure for publicizing the PPSG message and resources and introducing the PPSG to the media has been developed, although final design and printing have been delayed by uncertainty about our move to a new location.

7. Website

- The website is periodically checked and updated to ensure the links are working.

- Three major new products have been added: (1) "Trends in Use and Abuse of Opioid Analgesics," (2) *Achieving Balance in Federal and State Pain Policy: A Guide to Evaluation*, and (3) ***Annual Review of State Pain Policies, 2000*** .

- The comprehensive database of the full text of all state pain policies is updated as new policies are adopted.

- The PPSG website receives an average of 3,000 users/10,000 hits/month.

8. Participation in list serves

- PPSG staff monitor and participate in several national listserves about pain management, end-of-life care and controlled substances regulation. We frequently provide comments, accurate information in response to questions, and links to key resources that respond to topics being discussed.

9. OTHER

PPSG posted a question on the Last Acts website in order to present a case of physician being disciplined in Canada–precipitating an outpouring of cries that this was an attack on pain management. We presented facts of the case, and asked Dr. David Weissman to respond, which he did, making it perfectly clear that the physician's practice was substandard.

PPSG has assisted several of the Last Acts communications firms to develop various products, including reports on our work, policy briefs and audio-tapes.

III. TECHNICAL ASSISTANCE

PPSG has provided technical assistance to a variety of individuals and groups including the American Bar Association, the California State Board of Pharmacy, and the Hawaii Cancer Pain Initiative, and pain management and end of life care organizations in Hawaii, Kansas, Maine, New Mexico, Texas, Wisconsin and Michigan.

For example, PPSG responded to a request from the Commission on End of Life Care Committee on Prescription Drugs and the Michigan Hospice and Palliative Care Organization by providing a written critique of their recommendations to change state regulatory requirements relating to the use of controlled substances for pain management and end of life care. Members of the PPSG participated in a conference call with the Michigan committee to discuss their future steps.

PPSG helped to organize and moderate a summit meeting of health care professionals, drug law enforcement and medical regulation from Maryland, West Virginia and Virginia. The objective was to address health care professionals' concerns about being 'squeezed' between new pain accreditation standards and their fears of being investigated for prescribing 'too much.'

Staff members have contributed to many national conferences and meetings, including those of Last Acts; Midwest Bioethics; the Community-State Partnerships; the American Alliance of Cancer Pain Initiatives; the American Pain Society; the American Pharmaceutical Association; the American Society of Law, Medicine & Ethics; the National Association of Boards of Pharmacy; the National Association of State Controlled Substances Authorities; and Pain Management & Chemical Dependency. The National Council of State Legislatures has indicated its desire for ongoing collaboration with the PPSG.

Presently, PPSG is organizing an exploratory meeting to provide an opportunity for the US Drug Enforcement Administration and key pain and end of life organizations to review the situation with regard to the outbreak of abuse of oxycodone and discuss responses.

IV. FEEDBACK/HONORS

PPSG products were recognized by the administrator of the New York Board of Professional Medical Conduct. She told us that our work had played a major role in development of the Board's recent policy statement about the use of controlled substances for pain management (enclosed), which includes many positive statements and none that are negative according to PPSG policy evaluation criteria.

The immediate past president of the Missouri Medical Board stated that he wished he could rewrite our state pain law after reading the PPSG Evaluation Guide.

The PPSG website received StudyWeb's® Academic Excellence Award as a premier site for educational resources relating to Social Studies and Law.

The PPSG website was complimented by the President of Liquid Streaming®, a website consulting firm in New York, who stated during a meeting of pain management experts that the PPSG website was "one of the easiest medically-related websites to navigate to find important policy and legal information."

Mr. Joranson accepted the invitation of Dr. Russell Portenoy to become a member of the Editorial Advisory Board of the Journal of Pain and Symptom Management.

V. NEXT STEPS

In the next few months we will start the year-two content evaluation of medical board policies. We will compare medical board policies developed before the Federation of State Medical Board's Model Guidelines with those adopted afterwards to determine whether later policies are more balanced, whether they are more direct in addressing physicians' concerns about regulatory scrutiny, and whether they are more likely to use accurate terminology related to pain and addiction.

Further improvements will be made to the website, and our activities to provide information and technical assistance will continue.

In the near future we will submit to RWJF a concept paper for discussion in regard to possible projects.

VI. RECENT PUBLICATIONS

Gilson AM, Joranson DE, Ryan KM. Medical use and abuse of opioids. *Journal of Pharmaceutical Care in Pain & Symptom Control.* 2000;8(4):1-4.

Gilson AM, Ryan KM. Midwest program feature: The University of Wisconsin Pain and Policy Studies Group. *Midwest Pain Society Update.* 2000;Spring/Summer:6.

Gilson AM, Ryan KM, Maurer MA. A bibliography of recent pharmaceutical care articles on pain management and end-of-life care issues. *Journal of Pharmaceutical Care in Pain & Symptom Control.* 2000;8(4):49-56.

Joranson DE, Gilson AM. Pharmacists' knowledge and attitudes about opioid pain medications in relation to federal and state policy. *Journal of The American Pharmaceutical Association.* 2001;41(2):213-200.

Joranson DE, Gilson AM, Ryan KM, Maurer MA, Nischik JN, Nelson JM. *Achieving Balance in Federal and State Pain Policy: A Guide to Evaluation.* The Pain & Policy Studies Group, University of Wisconsin Comprehensive Care Center. 2000.

Joranson DE, Maurer MA, Gilson AM, Ryan KM, Nischik JN. *Annual Review of State Pain Policies, 2000.* The Pain & Policy Studies Group, University of Wisconsin Comprehensive Care Center. 2001.

Joranson DE, Ryan KM, Gilson AM, Dahl JL. Trends in medical use and abuse of opioid analgesics. *Journal of the American Medical Association.* 2000;283(13):1710-1714.

Joranson, DE. Regulatory Issues in Pain Management *Journal of the American Pharmaceutical Association* 2000; 40 (5): S60-S61.

VII. PENDING PUBLICATIONS

Gilson AM, Joranson DE. Controlled substances and pain management: Changes in knowledge and attitudes of state medical regulators. *Journal of Pain & Symptom Management.* In press. Received final galleys on 1-8-01, which were returned on 1-10-01; awaiting publication of the article.

Joranson DE, Carrow GM, Ryan KM, Schaefer L, Gilson AM, Good P, Eadie J, Peine S, Dahl JL. Pain management and prescription monitoring. *Journal of Pain and Symptom Management.* In review. Manuscript submitted 1-19-01.

Joranson DE, Gilson AM. Federal and state policy issues in the use of opioids for treatment of pain in patients who abuse controlled substances. *Principles of Addiction Medicine* (Third Edition). Manuscript submitted 11-20-01; awaiting reviewers' comments.

Joranson DE, Gilson AM, Dahl JL, Haddox JD. Pain management, controlled substances, and state medical board policy: A decade of change. *Journal of Pain & Symptom Management.* Manuscript submitted 2-28-01.

Targeted End-of-Life Projects Initiative
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Federal and State Policy Issues in the Use of Opioids for Treatment of Pain in Patients who Abuse Controlled Substances

David E. Joranson[1], MSSW; Aaron M. Gilson[1], Ph.D.

[1] Pain & Policy Studies Group, University of Wisconsin-Madison, Comprehensive Cancer Center

Address correspondence to:

David E. Joranson, MSSW

Pain & Policy Studies Group

1900 University Avenue

Madison, WI 53705

Tel: (608)263-7662

Fax: (608)263-0259

joranson@facstaff.wisc.edu

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It is well recognized that pain is prevalent in cancer and in other diseases and conditions, especially near the end of life (Bernabei et al., 1998; Cleeland et al., 1997; Ferrell, Juarez, & Borneman, 1999; Nowels & Lee, 1999; SUPPORT, 1995). Often, pain is not treated adequately. Unrelieved pain can impair all aspects of ordinary life activities and can lead to a patient's wish for death (Institute of Medicine, 1997). Relief of pain improves quality of living and can decrease suffering in the advanced stages of disease (WHO, 1986).

There are many pharmacologic and non-pharmacologic treatments that may be used to relieve pain. Opioid analgesics such as morphine are safe and effective for the medical management of pain, especially moderate to severe pain due to cancer (Jacox et al., March 1994; Portenoy, 1989; 1996; WHO, 1996). Opioids must be available when and where patients need them, especially when pain is severe (Institute of Medicine, 1997; WHO, 1990). Physicians, pharmacists and nurses must be able to prescribe, administer and dispense opioids according to individual patient needs (WHO, 1996). Historically, the use of opioids has been marginalized due to concerns about side-effects and abuse liability. The use of opioids to manage chronic non-cancer pain is becoming increasingly recognized. Even so, some patients find it difficult to obtain this essential medication; this is especially true for patients in pain who have a history of drug abuse or are using drugs for non-therapeutic purposes (Portenoy, 1996; Savage, 1999).

This article reviews the laws, regulations, and medical board policies that govern the use of opioids, including some that impede access to appropriate pain management for patients who currently abuse, or have abused, controlled substances.

Policies Governing Drug Availability

Before presenting specific policy language, brief definitions will be provided about the types of policies that will be discussed.

"Law" is a broad term that refers to rules of conduct with binding legal force adopted by a legislative or other government bodies at the international, federal, state or local levels. Laws also can be found in treaties, constitutional provisions, decisions of a court, statutes and regulations.

A "regulation" is an official rule issued by agencies of the executive branch of government. They are usually found in a state's administrative code or code of regulation. Regulations have the force of law, and are intended to implement or interpret laws that grant regulatory authority to an agency, often to establish what conduct is or is not acceptable for those regulated by the agency (such as physicians, pharmacists, and nurses). Regulations of state agencies should not exceed the scope of the agency's statutory authority.

"Guideline," as used here, means an official policy statement that is issued by a government agency, such as a state medical board, to express it's attitude or position on a particular matter. While guidelines themselves do not have binding legal force, they may outline parameters or standards of conduct for those who are regulated by the agency. For example, a number of state medical boards have issued guidelines regarding the medical use of opioids that define the conduct the board considers to be within, as well as outside of, the professional practice of

medicine. Some pharmacy and nursing boards have issued similar guidelines. Guidelines also include policy statements that may appear in a position paper, report, article, or agency newsletter.

International Policy: The Principle of "Balance"

The prescribing and dispensing of opioids[1] is governed by international treaties, U.S. federal law and regulations, and state laws and regulations. Although the singular purpose of these policies typically is perceived to be the control of diversion and the prevention of illicit drug use, drug control policy intends for there to be a second and equally important purpose – that of ensuring drug *availability*. Opioids are necessary for relief of pain and must be adequately available for medical purposes (United Nations, 1977a). Recognizing the presence of both control and availability in public policy is referred to as a "balanced" approach (Joranson & Dahl, 1989; Joranson, 1990a; Joranson & Gilson, 1994a). In achieving a proper balance between availability and control, the United Nations drug control authorities assert that efforts to prevent drug abuse and diversion should not interfere with the availability and medical use of controlled drugs (United Nations, 1977a; 1977b).

U.S. Federal Policy

Many prescription drugs, including opioid analgesics, are approved as both safe and effective for human use under medical supervision by the U.S. Food and Drug Administration

[1] Opioids, often referred to by regulatory agencies as "narcotic drugs," is a legal term that includes opiates and opioids, as well as cocaine and marihuana.

(FDA), according to authority under the Federal Food, Drug and Cosmetic Act of 1962 (FFDCA). Prescribing decisions are medical decisions; physicians generally are allowed to prescribe for a medical purpose and in the interest of the patient according to their best judgement (Federal Register, 1975). Prescription drugs may be prescribed for other than their specifically labeled indications or recommended doses if there is a medical rationale (Federal Register, 1983). FDA does not regulate medical practice (United States vs. Evers, 1981). The states, not the federal government, govern the practice of medicine (Joranson & Gilson, 1994a).

In addition, opioid analgesics are subject to controlled substances policies because of their abuse liability. The Controlled Substances Act (CSA, 1970) is a federal law that establishes the U.S. system of drug control and is intended to accomplish both goals of control and availability, paralleling the international treaties. Availability is accomplished through a regulated distribution system that governs import, manufacture, distribution, prescribing, dispensing, and possession. Licensed professionals may prescribe, dispense, and administer controlled drugs for legitimate medical purposes and in the course of professional practice if they have a state license to practice their profession and a valid controlled substances registration from the Drug Enforcement Administration (DEA) (DEA, 1990). To prevent diversion, the CSA establishes a system of requirements, penalties, security, record-keeping and monitoring. The Code of Federal Regulations (CFR) (Title 21, Chapter 2) is the regulation that implements federal law. The CFR is administered by the DEA

The CSA recognizes that controlled substances are necessary for public health and that availability of prescription controlled substances must be ensured. The CSA states that "many of the drugs included within this title have a useful and legitimate medical purpose and are necessary to maintain the health and general welfare of the American people" (p. 834).

CSA Drug Schedules

The CSA classifies controlled substances into five schedules; each carries different penalties for unlawful uses; requirements for prescriptions also vary depending on the schedule. Schedule I lists the drugs that have no accepted medical use and are available only for scientific research, such as marijuana, methaqualone, and the opioids such as heroin. Schedules II-V contain drugs that have been approved by the FDA for medical use and have an abuse potential, including the opioids. Opioids with the highest potential for abuse (and which also are indispensable for relief of pain) are placed in Schedule II. Schedule II drugs include morphine, hydromorphone, oxycodone, meperidine, fentanyl. Schedule III contains drugs with lower abuse potentials (as well as important medical uses) than either Schedules I or II, and include opioids such as hydrocodone and codeine combinations. Schedule IV includes opioids with important medical uses, such as dextropropoxyphene and codeine compounded in smaller dosages. Schedule V drugs have the lowest abuse potential and includes opioids primarily for medical use as antitussives or antidiarrheals.

Federal Laws Related to Opioid Prescribing

All persons or business entities must be registered with the DEA in order to manufacture, order, prescribe, or dispense controlled substances. All registrants' purchases must be made using a special triplicate order form (not to be confused with the triplicate prescription form that used to be required in several states) to monitor all transfers of controlled substances within a "closed distribution system." Prescriptions for Schedule II drugs must be in written form and may not be refilled, while five refills are permitted for drugs in Schedules III and IV. Federal law allows oral prescriptions of controlled substances in Schedule II in medical emergencies and

under specific circumstances (21 CFR §1306.11(d)). Federal law also allows for the partial dispensing (21 CFR §1306.13) and faxing (21 CFR §1306.11(a)) of Schedule II prescriptions under certain circumstances. Federal laws and regulations do not limit the amount of the prescription, the duration of prescribing, nor the period for which a prescription is valid. There are penalties, both criminal and civil, for violation of federal requirements.

Under the CSA, it is not considered to be a legitimate medical purpose, and is therefore unlawful, to prescribe narcotic drugs for the purpose of maintenance or detoxification treatment of narcotic addiction; this activity requires federal registration as a Narcotic Treatment Program (NTP). NTPs may dispense but not prescribe only those narcotic drugs approved for this purpose, such as methadone, and must comply with federal and state methadone program regulations. It is important to note that methadone may be prescribed and dispensed as an analgesic by physicians and pharmacists with controlled substances registrations, just as one would prescribe another Schedule II opioid analgesic.

State Policies

The regulation of medical practice occurs at the state, not the federal, level. Therefore, numerous state laws, regulations, and other governmental policies may further limit medical practice with controlled substances. State legislatures have adopted statutes to protect the public; these provide authority for a state agency to license and discipline members of the medical professions. The law creates a board, such as a Board of Medical Licensure or Boards of Pharmacy or Nursing, that is responsible for licensing the members of the profession, as well as disciplining licensees for violation of standards of professional conduct found in state statutes or regulations.

Boards may adopt regulations to implement the law governing medical practice; a board's rule-making procedures are a matter for public input and public record. Typically, there is a fixed number of board members also are appointed by the Governor for staggered terms. Sometimes this is done in consultation with the profession's state society. Board investigation of a licensee may be initiated by a complaint or by referral from another agency.

Boards differ greatly as to the procedures used for initial inquiry and investigation into complaints; some boards, by law, are required to investigate each complaint received; others can exercise discretion. In some states, the mere filing of a complaint against a physician is a matter of public record. Investigations may be prompt, and may be dropped due to insufficient evidence, or may proceed to disciplinary action. Sometimes these proceedings take several years before they are concluded. If the board finds there has been one or more violations, a range of actions may be considered depending on the nature of the violation, and may include a warning, education, limitation or removal of prescribing privileges, or suspension or revocation of the professional's license. Board disciplinary actions are reviewable by the state courts. Boards also manage programs to assist in the identification, treatment and recovery of impaired licensees.

The licensing boards for each health-care profession have a national organization; for medical boards, it is the Federation of State Medical Boards of the United States (FSMB); for pharmacy boards, it is the National Association of Boards of Pharmacy; for nursing boards, it is the National Council of State Boards of Nursing. These organizations sponsor a number of activities, such as: (1) annual meetings, (2) task forces to study specific issues relevant to the regulation of that profession, and (3) technical assistance, training, policy development and preparation of model laws and regulations, and dissemination of information, including newsletters, statistics about licensees and discipline.

In addition to professional practice policy, the states have adopted versions of the CSA in order to apply state laws to the control of controlled substances. Typically, these laws are patterned after the model Uniform Controlled Substances Act (UCSA) prepared by the National Conference of Commissioners on Uniform State Laws (NCCUSL) (August, 1970; July, 1990). These state laws permit prescribing, dispensing, or administering of controlled substances for legitimate medical purposes, although most do not specifically recognize the essential medical value of controlled substances when they were adopted, as did the CSA. A revised model UCSA has been prepared to correct this and other deficiencies (NCCUSL, July, 1994), but only a few states have adopted the changes, including Washington, Colorado, and Wisconsin. The criminal provisions of the state controlled substances laws are enforced by state and local police agencies, while departments of regulation and licensing and pharmacy examining boards manage the administrative aspects, such as drug scheduling. Some state agencies have issued regulations that govern the prescription and dispensing of controlled substances more strictly than under federal law (National Association of Boards of Pharmacy, 1998; Joranson & Gilson, 1994a). Penalties for violation of prescribing requirements vary widely.

In addition, a number of states have laws that establish Prescription Monitoring Programs. At this writing, there are seven states with laws requiring use of a special prescription form and Electronic Data Transfer (EDT) to monitor prescriptions of controlled substances. Typically, these programs apply to any medication in Schedule II, including the opioids such as fentanyl, hydromorphone, oxycodone, meperidine, and morphine. In these states, physicians are required to obtain a special prescription form, often from the state agency that monitors the prescriptions. Nine states use EDT alone to monitor such prescriptions. These programs do not require physicians to use special prescription forms. The patient simply takes the regular

prescription form to the pharmacy, and the pharmacist is responsible for relaying the prescription information electronically to the relevant state agency. States wishing to adopt a prescription monitoring program for the first time opt for EDT systems alone. States that have required special prescription forms in the past have added EDT.

What is "Addiction"?

The use and definition of terms associated with drug abuse phenomena, such as "addiction," remains a point of confusion. Such confusion originates in part from official definitions and expert opinions that have traditionally characterized addiction as primarily physical dependence, as indicated by the withdrawal syndrome. In 1969, the World Health Organization (WHO) replaced "addiction" and "habituation" with the term "drug dependence." The use of drug dependence was a major change; it was defined primarily as the use of a drug for its psychic effects, and characterized by compulsive use. Physical dependence (as evidenced by withdrawal syndrome) nor tolerance, by themselves or together, were no longer sufficient to define drug dependence. The distinction between physiological adaptation to a drug (evidenced by the development of withdrawal syndrom and tolerance) and compulsive use despite harm is reflected in the two primary diagnostic classification systems used by health-care and mental-health professional: the WHO's *International Classification of Mental and Behavioural Disorders* (10th Edition) (ICD-10) and the American Psychiatric Association's *Diagnostic and Statistical Manual* (4th Edition) (DSM-IV). The criteria to diagnose "dependence syndrome" and "substance dependence" from the ICD-10 and DSM-IV, respectively, include both withdrawal and tolerance. However, compulsive use that contributes to personal impairment or distress must

also be present for the diagnosis to be possible. As a result, a maladaptive pattern of behavior (as represented by a compulsive desire to take the drug) is the *essential* characteristic of "dependence."

In 1993, the WHO Expert Committee on Drug Dependence further clarified that cancer patients who use opioids should not be considered dependent solely on the basis of the development of a withdrawal syndrome that would occur if the opioid medication were to be stopped. The WHO has further reinforced this notion by stating that:

> ...dependence should not be a factor in deciding whether to use opioids to treat the cancer patient with pain. (WHO, 1996, p. 41)

The accurate use of terminology is central to shaping a "balanced" policy on drug control especially in the United States, where prescribing of opioids to maintain addiction is illegal. It is neither appropriate nor necessary to use terms to refer to persons as "addict" or "habitué" in controlled substance or professional practice policy. If these terms are used, they should be defined so there is no possibility of confusion with pain patients who may be tolerant and/or physically dependent (Joranson, 1990b; NCCUSL, 1990, 1994). It is now recognized that tolerance and physical dependence denote normal physiological adaptation of the body to the presence of an opioid; thus, a patient being treated with opioid analgesics may develop physical dependence and/or tolerance. Confusion of addiction or drug dependence with physical dependence or tolerance can result in labeling a pain patient as an "addict" or "drug dependent," and increase the risk of inadequate pain treatment.

Indeed, Weissman and Haddox (1989) have defined the term "pseudoaddiction." This

term characterizes a situation in which the pattern of pain relief-seeking behavior by a pain patient who is receiving inadequate pain management is mistaken by health-care providers for drug-seeking behavior characteristic of addiction or dependence. The inappropriate perception of pain patients as drug-seekers or addicts may result in denial of the opioid prescriptions they may need pain management. There has been at least one documented case where an inadequately treated pain patient illegally called in controlled substances prescriptions only to obtain pain relief. Prosecutors viewed the patient as a drug abuser, even though evaluation for pain was positive and was negative for addictive disease (State of Wisconsin vs. Holly, 1997).

Policies That Can Affect Prescribing to Pain Patients who Abuse Controlled Substances

Federal Policy

Federal policy has several provisions that will be examined.

Definition of "addict." The CSA defines a class of persons called "addict" as an individual who:

> habitually uses any narcotic drug so as to endanger the public morals, health, safety, or who is so far addicted to the use of narcotic drugs as to have lost power of self-control with reference to his addiction. (p. 836)

The definition is circular and uses archaic terminology. However, since the main component of

the definition is loss of control and harm, the potential for this term to confuse an addict with a pain patient is low. It is possible, however, that this old definition assumes that addiction means physical dependence/withdrawal, since this term appeared in law long before the more recent distinction was made between physical dependence and compulsive behaviors that characterize addiction.

This latter possibility is supported by the federal regulation that governs dispensing of methadone for maintenance or detoxification treatment of narcotic addiction in an NTP. Eligibility for admission to an NTP requires that the person be "narcotic dependent," defined as "an individual who physiologically needs...a heroin or morphine-like drug to prevent the onset of signs of withdrawal" (CFR 291.505(a)(5)). Anecdotal reports suggest that some chronic pain patients are indeed being admitted to NTPs only to obtain methadone for pain relief (Joranson, 1997). A California NTP director has estimated that approximately 200 patients had been admitted to NTPs during the mid-1990s for the treatment of chronic pain conditions, and that these were individuals who had demonstrated no behavioral characteristics of addiction (Tennant, 1996). Thus, federal regulations contain language that confuses physical dependence with addiction and allows pain patients to be admitted to addiction treatment programs.

State Policies

Studies have demonstrated that state policies are not as balanced as international and federal policy (Joranson, 1990a; Joranson & Gilson, 1994a). Many state laws do not recognize the value of controlled drugs to public health as does federal law. States have laws, regulations, or other governmental policies that restrict prescribing and dispensing of opioids more than federal policy; such policies have the potential to interfere with patient care decisions that should

be made by health-care professionals, rather than by government officials.

Studies of regulatory impediments to pain in state policies began in Wisconsin in the mid-1980s (Hill, 1989; Joranson & Dahl, 1989; Joranson & Gilson, 1996; 1997). Subsequently, a succession of reports on inadequate pain management by national expert groups identified regulatory impediments in state policies (Federation of State Medical Boards of the U.S., May 1998; Institute of Medicine, 1997; Jacox et al., March 1994; Merritt, Fox-Grage, & Rothouse, 1998; National Conference of Commissioners on Uniform State Laws, July 1990; July 1994). Many of the restrictive provisions that have been identified in state policies date back as far as 25 years, and appear to have been based on now-outdated conceptions about addiction and side-effects of opioid analgesics.

A comprehensive criteria-based evaluation of strengths and weaknesses of policies in 17 states has been accomplished (Joranson, Gilson, Ryan, Maurer, & Nelson, July 1999). Evaluation of the remaining states and federal policy will be completed in 2000. This evaluation has identified a number of provisions that have the potential to impede pain management, as well as a number which have the potential to enhance pain management. Some states restrict the quantity of controlled substances that can be prescribed at one time, or limit the validity of a prescription to a few days. A number of states have imprecise terminology that could confuse persons with addictive disease or drug dependence with pain patients. One example of such language can be found in Oklahoma (Oklahoma Uniform Controlled Dangerous Substances Act, §2-101(15)), which uses a definition of "drug-dependent person" that is fairly common in state laws:

> a person who is using a controlled dangerous substance and who is in a state of

psychic *or* physical dependence, or both, arising from administration of that controlled substance on a continuous basis.

Several states also require physicians to report to a government agency patients to whom they prescribe controlled substances for more than several months. Such a policy can create an additional administrative burden for the physician. In addition, such a policy can cast a shadow over the treatment of pain in patients with a substance abuse history and in those pain patients who currently use drugs for non-therapeutic purposes. For example, these clinical situations occur with patients who have AIDS. Some states, including New York and Texas, have revised their definitions to permit the treatment of substance abusers with controlled substances. The full text of state pain policies can be found on the PPSG website at www.medsch.educ/painpolicy.

Intractable Pain Treatment Acts. Since 1989, a number of state legislatures have adopted Intractable Pain Treatment Acts (IPTAs). A review of IPTAs suggests that, although the intent of these policies is to address physician fear of regulatory scrutiny, they also have provisions that if strictly implemented would restrict physician prescribing and patient access to opioid analgesics (Joranson, 1995; Joranson & Gilson, 1997). Potentially restrictive language can be found in most IPTAs' definition of intractable pain. The Texas IPTA (Texas Intractable Pain Treatment Act, Article 4495c) was the first intractable pain-related policy and has served as a model for five of the other nine states (56%) with IPTAs. It defines "intractable pain" as:

...a pain state in which the cause of the pain *cannot* be removed or otherwise treated and which *in the generally accepted course of medical practice* no relief or cure of the cause of the pain is possible or none has been found after reasonable

efforts. (emphasis added)

Taken in the context of a law relating to the use of opioid analgesics, such a definition implies that a physician's prescribing of controlled substances for chronic pain is outside of generally-accepted medical practice unless done within the parameters of the IPTA. Further, limiting the use of opioids only to those patients were other efforts have failed implied that use of opioids is a treatment of last resort. Thus, despite the intent of IPTAs to encourage pain management, these laws appear to position the use of opioids nearer to the edges of medical practice rather than at the center.

A balanced approach to drug policy will recognize that physicians should make medical decisions based on the treatment needs of individual patients. However, before prescribing opioids, some IPTAs require the physician to obtain a consultation or an evaluation of every pain patient by a specialist in the organ system believed to be the cause of the pain, in order for the physician to be immune from discipline. Such a governmental requirement appears to further marginalize pain management and does not take into account the expertise of the physician or the patient's needs, which in some cases could be relatively straightforward or of an immediate nature. Such policies may discourage pain management because of the increased time and administrative burden for the physician as well the possibility of increased cost to the patient.

Further, immunity from discipline under some IPTAs excludes a physician's prescribing to the entire class of patients who use drugs non-therapeutically and, therefore, may have the unintended effect of excluding substance abusers from pain management (Joranson & Gilson, 1994b). Such provisions appear to conflict with federal policy which only prohibits physicians from prescribing narcotic drugs for the *purpose* of maintaining narcotic addiction, but does not

prohibit prescribing of opioids to *persons* who have pain and also addictive disease. Such state policies have the clear potential to interfere with the treatment of pain in persons who have addictive disease and who have cancer or AIDS.

State Medical Board Policies. A recent content evaluation of state medical board guidelines found that almost 80% of these policies established recommendations or specific requirements regarding prescribing of opioids for patients with a history of drug abuse (Monterroso, Gilson, Williams, Nelson, Joranson, October 1997):

- to evaluate each patient for a history of addiction or for current addiction;
- to consult another physician about the diagnosis;
- to provide extra care and special attention;
- to establish treatment according to the possibility of drug misuse; and
- to be "vigilant" with regard to drug-seeking behaviors.

Several policies also stated that it would be inappropriate medical practice to prescribe controlled substances to a person who used drugs non-therapeutically. In sharp contrast, one state's policy stated that:

> "Addicts can be the legitimate victims of pain, independent of their addiction...although it is appropriate to prescribe for pain control, extra diligence must be exercised with such patients." (New Mexico Board of Medical Examiners, July 1997, p. 1).

It is evident that some state medical board policies that are intended to improve access to pain management do not contain language that would include patients who use (or have used) drugs for non-therapeutic purposes.

Perceived Risk of Regulatory Scrutiny

A number of studies and articles report that physicians are reluctant to prescribe opioid analgesics because they are concerned about being investigated by a regulatory agency (Institute of Medicine, 1997; Hill, 1993; Joranson & Gilson, 1994b; Haddox & Aronoff, 1998; Martino, 1998). A pilot survey of Wisconsin physicians conducted in 1991 found that more than one-half reported that they would reduce the dose or quantity, reduce the number of refills, or choose a drug in a lower schedule because of concern about regulatory scrutiny (Weissman, Joranson, & Hopwood, 1991). In addition, 40% of the physician-members of the American Pain Society (APS) agreed in 1991 that their prescribing of opioids for chronic nonmalignant pain was influenced by legal concerns (Turk, Brody, & Okifuji, 1994). Although these studies suggest that physicians fear discipline from a regulatory agency, is this fear warranted?

In 1991, all state medical board members in the U.S. were surveyed to learn more about whether regulators' knowledge and attitudes about the medical use of opioids for chronic cancer and non-cancer pain could pose a risk to the physician who prescribe opioid analgesics (Joranson, Cleeland, Weissman, & Gilson, 1992). Board members were asked to give their opinion about the legality and medical acceptability of prescribing opioids for more than several months in four patient scenarios involving malignant and non-malignant pain, with and without a history of drug abuse of the opioid type. There were five possible responses: (1) lawful and generally acceptable medical practice, (2) lawful but generally not accepted medical practice and

should be discouraged, (3) probably a violation of medical practice laws or regulations and should be investigated, (4) probably a violation of federal or state controlled substances laws and should be investigated, and (5) don't know.

Only 75% of medical board members were confident that prescribing opioids for chronic cancer pain was both legal and acceptable medical practice; 14% felt it was legal but would discourage it; 5% believed that the practice was illegal and should be investigated. If the cancer patient with chronic pain had a history of opioid abuse, less than half of the respondents (46%) were confident in prescribing opioids and 22% would discourage the practice. Fourteen percent considered the practice to be a violation of medical practice law and 12% viewed it as a violation of controlled substances laws. When the patient's chronic pain was of non-malignant origin, only 12% of respondents were confident that prescribing opioids was both legal and medically acceptable; 47% would discourage it; and nearly a third recommended investigating the practice as a violation of law. Finally, only 1% of respondents viewed the prescribing of opioids for more than several months to a patient with chronic non-malignant pain and a history of opioid abuse as legal and acceptable medical practice.

Overall, it appears that many medical board members lacked knowledge about the use of opioids and other controlled substances to manage pain. To varying degrees they would discourage or investigate the prescribing of opioid analgesics for chronic pain, particularly if the patient does not have cancer but especially if the patient had a history of drug abuse. It is important to recognize that the presenting problem in each scenario was pain, not addiction.

Results from this survey also suggested that there was confusion about the meaning of addiction. Respondents were asked to define "addiction" by selecting one or more appropriate terms from the following list: physical dependence, tolerance, psychological dependence, other,

and don't know. Eighty-five percent of board members included physical dependence as a characteristic of addiction. Only 10% of respondents defined addiction solely by psychological dependence, whereas 21% and 1% viewed it to be only physical dependence or tolerance, respectively. These responses were given even though addiction is not established by the presence of physical dependence or tolerance, but rather by a maladaptive pattern of use including loss of control, adverse consequences of use, and unwarranted preoccupation (American Academy of Pain Medicine/American Pain Society, 1997; American Pain Society, 1999; American Society of Addiction Medicine, 1998). It was evident that medical board members needed updated information about the use of opioid analgesics and law governing controlled substances. Therefore, we offered to provide workshops on pain management to any interested state medical board.

From 1994 to 1998, state medical boards have participated in 11 pain management workshops sponsored by the PPSG and the FSMB. During the same period, boards began to adopt guidelines (and in a few cases, regulations) to encourage improved pain management and to dispel physicians' fear of discipline (Joranson & Gilson, 1996; Joranson, Gilson, Dahl, & Haddox, in review).

Model Guideline

In 1998, the FSMB adopted a document entitled "Model Guidelines for the Use of Controlled Substances for the Treatment of Pain." The purpose was to promote positive state medical board pain policy and greater policy consistency between the states, The Model Guidelines were developed as a cooperative effort between the FSMB and representatives of state medical boards, the PPSG, the APS, the American Academy of Pain Medicine, and the

American Society of Law, Medicine and Ethics. The FSMB disseminated the Model Guidelines to each state medical board with a request that they be considered and adopted as policy.

The Model Guidelines state that opioid analgesics may be necessary for the treatment of pain, including pain associated with acute, cancer, and non-cancer conditions. If adopted by state medical boards, the positive language would communicate to medical professionals that their licensing board recognizes there are health benefits to using controlled substances as part of legitimate medical practice.

The Model Guidelines address directly the limitations inherent in current board policies, as identified by the content evaluation. Although many existing medical board policies do not have a clear statement of purpose, the model guidelines encourage pain management, and clarify that effective pain management is expected in good medical practice. In addition, the policy recognizes that physicians are concerned about regulatory scrutiny and provides them with information about how the board distinguishes legitimate medical practice from unprofessional conduct. The Model Guidelines make it clear that judgements about the legitimacy of a medical practice will be based on the treatment outcomes for patients, rather than on the amount or duration of prescribing.

The Model Guidelines also contain a set of recommended treatment parameters for using controlled substances for pain management, which are based on principles of good medical practice. Seven outlined treatment steps are included: (1) medical history and physical examination, (2) treatment plan with identified objectives, (3) informed consent to treatment, (4) periodic review of treatment, (5) consultation as necessary, (6) accurate and complete medical records, and (7) compliance with both federal and state controlled substances policy. The Model Guidelines recognize the need for flexibility, stating that a physician may deviate from the

guidelines for good cause shown (FSMB, May, 1998).

Another important improvement of the Model Guidelines is the definition of addiction-related terms, which are sometimes used inconsistently or inappropriately in existing board policies. Definitions that conform to currently accepted medical standards are provided for "addiction," "physical dependence," "psychological dependence," "tolerance," and "pseudo-addiction." These definitions clarify that physical dependence or tolerance do not characterize addiction. The knowledge and appropriate use of correct terms decreases the likelihood that pain patients will be viewed as "addicts" by health-care professionals (Joranson & Gilson, 1998).

The Model Guidelines do not exclude patients with addictive disease from treatment of pain with opioid analgesics. The FSMB recognized that the decision to prescribe controlled substances to a patient should be based on clinical findings in the individual patient; however, physicians are urged to "be diligent in preventing the diversion of drugs for illegitimate purposes" (FSMB, May, 1998, p. 1).

Conclusion

In recent years, pain management has become a higher priority in the U.S. health-care system. The use of opioids for the treatment of acute and chronic pain, both cancer and non-cancer related pain, in patients with histories of addictive disorders or drug abuse is lawful under Federal law. However, from this review of controlled substances and professional practice policy it is evident that some state policies and the views of some state medical board members may discourage the prescribing of opioid analgesics when needed by pain patients who have addictive disorders. It is necessary to identify and change such policies. Health-care professionals should be educated about treating pain in substance abusers, which remains a

complex and intensive task. Trained and experienced practitioners who also are knowledgeable about the policy in their state will be in a much better position to evaluate the medical needs of such patients.

References

American Academy of Pain Medicine and American Pain Society. *The use of opioids for the treatment of chronic pain: A consensus statement.* 1997.

American Pain Society. *Principles of Analgesic Use in the Treatment of Acute Pain and Cancer Pain.* 4th ed. Glenview, IL; 1999.

American Psychiatric Association. *Diagnostic and statistical manual of mental disorders* (Fourth edition). Washington, DC: APA, 1994.

American Society of Addiction Medicine. Policy statement: Definitions related to the use of opioids for the treatment of pain. *Journal of Addictive Diseases.* 1998;17:129-130.

Bernabei R, Gambassi G, Lapane K, et al. Management of pain in elderly patients with cancer. *JAMA.* 1998;279:1877-1882.

Cleeland CS, Gonin R, Baez L, Loehrer P, Pandya KJ. Pain and treatment of pain in minority patients with cancer. The Eastern Cooperative Oncology Group Minority Outpatient Pain Study. *Annals Intern Med.* 1997;127:813-816.

Code of Federal Regulations. Title 21. §291.505(a).

Code of Federal Regulations. Title 21. §1306.11(a).

Code of Federal Regulations. Title 21. §1306.11(d).

Code of Federal Regulations. Title 21. §1306.13.

Controlled Substances Act of 1970. Pub L No 91-513, 84 Stat 1242.

Drug Enforcement Administration. Physician's manual: an informational outline of the Controlled Substances Act of 1970. Department of Justice, Drug Enforcement Administration, 1990.

Federal Register 15393-94, 1975.

Federal Register 2673, 1983.

Federation of State Medical Boards of the United States. *Model guidelines for the use of controlled substances for the treatment of pain*. A policy document of the Federation of State Medical Boards of the United States, Inc. Euless, TX: FSMB, May, 1998.

Ferrell BR, Juarez G, Borneman T. Use of routine and breakthrough analgesia in home care. *Oncol Nurs Forum*. 1999;26(10):1655-1661.

Haddox JD, Aronoff GM. Commentary: the potential for unintended consequences from public policy shifts in the treatment of pain. J Law, Med & Ethics 1998;26(4):350-352.

Hill CS. The negative effect of regulatory agencies on adequate pain control. *Primary Care and Cancer,* 45-53, November 1989.

Hill CS Jr. The barriers to adequate pain management with opioid analgesics. Sem Onc 1993;20(2 Suppl 1):1-5.

Institute of Medicine. Approaching death: improving care at the end of life. Washington, D.C.: National Academy Press, 1997.

Jacox A, Carr DB, Payne R et al. Management of cancer pain. Clinical Practice Guideline. No. 9. AHCPR Publication No. 94-0592. Rockville, MD: Agency for Health Care Policy and Research, Public Health Service, U.S. Department of Health and Human Services, March 1994.

Joranson DE. Federal and state regulation of opioids. *Journal of Pain and Symptom Management,5*(Suppl), S12-S23, 1990a.

Joranson DE. A new drug law for the states: An opportunity to affirm the role of opioids in cancer pain relief. *Journal of Pain and Symptom Management, 5*(5): 333-336, 1990b.

Joranson DE. Intractable pain treatment laws and regulations. Amer Pain Soc Bull 1995;5(2):1-

Joranson DE, Gilson AM. Controlled substances and pain management: A new focus for state medical boards. *Federation Bulletin*. 1998;85(2):78-83.

Joranson DE, Gilson AM, Dahl JL, Haddox JD. Pain management, controlled substances, and state medical policy: A decade of change. *JAMA*. in review

Joranson DE, Gilson AM, Ryan KR, Maurer MA, Nelson JN. *Achieving Balance in State Pain Policy: A Guide to Evaluation, Part I.* Madison, WI: Pain & Policy Studies Group; July 1999.

Martino AM. In search of a new ethic for treating patients with chronic pain: what can medical boards do? J Law, Med & Ethics 1998;26(4):332-334.

Merritt D, Fox-Grage W, Rothouse M. *State initiatives in end-of-life care: Policy guide for legislators*. National Conference of State Legislatures, 1998.

Monterroso MM, Gilson AM, Williams CM, Nelson JM, Joranson DE. *A Comparison of State Medical Board Pain Guidelines with a National Model.* Poster presented at the 16th annual American Pain Society conference. New Orleans, LA; October 1997.

National Association of Boards of Pharmacy. *Survey of Pharmacy Law, 1998-1999.* Park Ridge, IL: NABP, 1998.

National Conference of Commissioners on Uniform State Laws. *Uniform Controlled Substances*

Act. St. Louis, MO: NCCUSL, August 1-8, 1970.

National Conference of Commissioners on Uniform State Laws. *Uniform Controlled Substances Act.* Milwaukee, WI: NCCUSL, July 13-July 20, 1990.

National Conference of Commissioners on Uniform State Laws. Uniform Controlled Substances Act. Chicago, IL: NCCUSL, July 29-August 5, 1994.

New Mexico Board of Medical Examiners. Guidelines on prescribing for pain. *Newsletter Information & Report.* 1997;2(1):1-3.

Nowels D, Lee JT. Cancer pain management in home hospice settings: a comparison of primary care and oncology physicians. *J Pall Care.* 1999;15(3):5-9.

Oklahoma Uniform Controlled Dangerous Substances Act. Title 63 Public Health and Safety. §2-101(15).

Portenoy RK. Cancer pain: Epidemiology and syndromes. *Cancer, 63, 2298-2307, 1989.*

Portenoy RK. Opioid therapy for chronic nonmalignant pain: clinicians' perspective. J Law, Med & Ethics 1996;24(4):296-309.

Savage SR. Opioid use in the management of chronic pain. Med Clinics of North Amer

1999;83(3):761-786.

State of Wisconsin vs. Holly. Case No. 96 CF 978, 1997.

SUPPORT Study Principle Investigators. A controlled trial to improve care for seriously ill hospitalized patients. The study to understand prognoses and preferences for outcomes and risks of treatments (SUPPORT). *JAMA*. 1995;274:1591-1598.

Tennant F. The dilemma of severe incurable, narcotic-dependent pain patients referred to narcotic treatment programs: Need for administrative, regulatory, and legislative relief. West Covina, CA: Research Center for Dependency Disorders and Chronic Pain Community Health Projects Medical Group, 1996.

Texas Intractable Pain Treatment Act. Title 71 Health-Public, Ch. 6, Article 4495c.

Turk DC, Brody MC, Okifuji EA. Physicians' attitudes and practices regarding the long-term prescribing of opioids for non-cancer pain. *Pain*. 1994; 59:201-208.

United Nations. *Single Convention on Narcotic Drugs, 1961, as-amended by the 1972 Protocol Amending the Single Convention on Narcotic Drugs*. New York, NY: UN, 1977a.

United Nations. *Single Convention on Psychotropic Drugs, 1971*. New York, NY: UN, 1977b.

United States vs. Evers, 643 F2d 1043 5th Circuit, 1981.

Weissman DE, Joranson DE, Hopwood MB. Wisconsin physicians' knowledge and attitudes about opioid analgesic regulations. Wisc Med J 1991;December:53-58.

Weissman DE, Haddox JD. Opioid pseudoaddiction - An iatrogenic syndrome. *Pain*, 36, 363-366, 1989.

World Health Organization. *WHO Expert Committee on Drug Dependence.* Sixteenth report. (Technical Report Series 407). Geneva, Switzerland: WHO, 1969.

World Health Organization. *Cancer pain relief.* Geneva, Switzerland, 1986.

World Health Organization. *Cancer pain relief and palliative care.* (Technical Report Series 804). Geneva, Switzerland: WHO, 1990.

World Health Organization. *The ICD-10 Classification of Mental and Behavioural Disorders. Clinical descriptions and diagnostic guidelines.* Geneva, Switzerland: WHO, 1992.

World Health Organization. *WHO Expert Committee on Drug Dependence* (Technical Report Series 836). Geneva, Switzerland: WHO, 1993.

World Health Organization. *Cancer pain relief with a guide to opioid availability.* Geneva,

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Pain Management, Controlled Substances, and State Medical Policy: A Decade of Change

David E. Joranson[1], MSSW; Aaron M. Gilson[1], Ph.D.; June L. Dahl[2], Ph.D.; J. David Haddox[3], DDS, MD

[1] Pain & Policy Studies Group; University of Wisconsin-Madison, Comprehensive Cancer Center; World Health Organization Collaborating Center for Policy and Communications

[2] Department of Pharmacology; University of Wisconsin-Madison, Medical School

[3] Purdue Pharma LP

Address correspondence to:

David E. Joranson, MSSW

Pain & Policy Studies Group

1900 University Avenue

Madison, WI 53705

Tel: (608)263-7662

Fax: (608)263-0259

joranson@facstaff.wisc.edu

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Abstract

Physicians report that concern about regulatory scrutiny and the possibility of unwarranted investigation and discipline from regulatory agencies affects negatively their prescribing opioid analgesics to treat pain. This article describes a 10-year program of research, education, and policy evaluation with state medical boards to increase understanding that the appropriate use of opioid analgesics for pain management is a legitimate medical practice. A survey of state medical board members conducted in the early 1990s led to a series of educational workshops for board members about pain management and controlled substances policy. During this period, a number of state medical boards adopted new pain-related policies. An evaluation of these policies was used to inform the development of model guidelines that medical boards can adopt to clarify state policy regarding the use of controlled substances for pain management. Recommendations are provided for further actions that state medical boards can take to address inadequate pain management and concerns about regulatory scrutiny.

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Introduction

There are many safe and effective treatments for pain, both pharmacologic and non-pharmacologic. Opioid analgesics are essential for the treatment of moderate to severe pain, especially acute pain [1,2] and cancer pain,[2-4] as well as for certain patients with chronic non-cancer pain.[5,6] Despite the availability of such treatments, the inadequate management of pain has been well documented in patients with a variety of diagnoses and conditions [7-11] and in a variety of health-care settings.[12-18]

A number of factors contribute to the undertreatment of pain, including physicians' fears of being investigated for excessive prescribing of opioids.[19-23] This article summarizes a program of research, education and policy evaluation to address this problem. The program was undertaken by the University of Wisconsin Pain & Policy Studies Group (PPSG), in cooperation with state medical boards and national pain associations. The program was developed in several stages, and included a national survey of state medical board members, educational workshops for board members, evaluation of medical board policies, and technical assistance to develop model state medical-regulatory guidelines for the use of controlled substances in pain management.

Physician Concern About Regulatory Scrutiny

A 1990 survey of oncologists that studied the reasons for inadequate cancer pain management found that 18% rated excessive regulation of analgesics as one of the top four

barriers.[24] Indeed, oncologists in several states have been investigated and prosecuted for prescribing opioids to cancer patients (who were by then deceased). Eventually the charges were dropped, but these events reached the news media, including cancer journals.[25]

A 1991 survey of Wisconsin physicians found that more than half would at least occasionally reduce dose, quantity or refills, or prescribe a drug in a lower schedule due to fear of regulatory scrutiny.[26] Concerns about investigation were least when opioids were prescribed for acute pain, but increased if prescribing was for chronic cancer pain; concern was greatest if prescribing was for chronic pain not related to cancer, or for patients with a history of drug abuse.

In that same year, a survey of physician-members of the American Pain Society (APS), 40% said that concerns about regulatory scrutiny rather than medical reasons led them to avoid prescribing opioids for chronic non-cancer pain patients.[23,27] In a national survey of physicians, respondents tended to agree that regulatory pressure restricted their use of opioids for patients with chronic non-cancer pain.[23] Indeed, the use of opioid analgesics for chronic non-cancer pain has been controversial and discouraged by some in both the pain and regulatory communities.[6,28,29] More recently, clinicians, researchers, and regulators have re-examined the use of opioids for chronic non-cancer pain, concluding that there is a role for opioids in carefully-selected patient populations.[5,30]

Research and Education with State Medical Boards

In 1991, following our survey of Wisconsin physicians, we surveyed all state medical board members.[31] The purpose was to assess whether board members' knowledge and attitudes

posed a threat to physicians who prescribe opioids for management of chronic cancer and non-cancer pain. With the cooperation of the Federation of State Medical Boards of the United States (FSMB), a confidential pre-tested questionnaire was mailed to all 627 state medical board members. A 50% response rate was achieved. Respondents represented 49 states, with a mean of six respondents per state. We summarize that portion of the results relating to board members' views about the legality of extended opioid prescribing.

Board members were asked their opinions about the legality and medical acceptability of prescribing opioids for more than several months to patients with different diagnoses, including a patient with chronic cancer pain and a patient with chronic non-cancer pain. The respondent could choose from five response options, that the prescribing practice was: (1) lawful and generally acceptable medical practice, (2) lawful but generally not acceptable and should be discouraged, (3) probably a violation of state medical laws or regulations and should be investigated, (4) probably a violation of federal or state controlled substances laws and should be investigated, and (5) don't know. It should be noted that federal policy recognizes that the use of opioids for pain, including for patients with chronic disorders, is a legitimate medical practice and therefore lawful.[21,32,33]

Only 75% of the respondents agreed that the prescribing of opioids for the cancer patient was legal and generally acceptable medical practice. Confidence in the legality of prescribing for the patient with chronic non-cancer pain was 12%; the majority of respondents would discourage this practice, or even investigate it as a violation of law. It is of interest that the respondents' median year of graduation from medical school was 1961. Most of these physician-board members received their medical training well before pain became a clinical science, before pain

relief had become a public health priority, and well before the growing recognition that opioids could be used for patients with chronic non-cancer pain.

The survey results suggested a need to update medical board members' knowledge about pain management and public policy. We published the results in the FSMB journal, the *Federation Bulletin*, in order to communicate directly with the medical boards. We offered to organize seminars about pain management for board members, believing that they would want to know about recent developments in pain management, and that they would respond to other physicians' concerns about being investigated for prescribing to treat chronic pain.

The PPSG and the FSMB cosponsored a series of 11 workshops on "Pain Management in a Regulated Environment" between 1994 and 1998. The faculty for all workshops were David E. Joranson, MSSW (representing the PPSG), June L. Dahl, Ph.D. (representing the APS), and J. David Haddox, DDS, MD (representing the American Academy of Pain Medicine [AAPM]). The faculty was knowledgeable in public policy, pharmacology, pain medicine and addiction medicine. The content of each workshop included the extent of the pain problem; the reasons for inadequate management of pain including exaggerated fear of addiction and concerns about regulatory scrutiny; methods for the assessment and treatment of pain; a review of recent advances in the understanding of pain physiology and opioid pharmacology; and the status of controlled substances and professional practice law, regulations, and medical board guidelines about the use of controlled substances for pain management.[34]

Overall, 297 representatives of state medical boards participated in the one-day workshops, representing 40 states and approximately 25% of the total board member population. Participants in the workshops included both physician and public members, as well as

investigators, attorneys and administrative staff.

The Evaluation of State Medical Board Policy

In the next phase of the program, we evaluated state medical board policies to better understand the potential for these policies to pose a threat to physicians who prescribe controlled substances for pain management. Medical board policies, or "guidelines," express the attitude of the board regarding controlled substances and pain management. We found that, 10 years ago, few medical boards had adopted policies relevant to controlled substances and the treatment of pain. By 1999, more than half of the state medical boards had adopted pain guidelines (see Figure 1). However, our evaluation found that only some of these encourage better pain management, address physicians' concerns about regulatory scrutiny, or clarify the board's view of role of opioids in pain management.[35] The full text for the medical board policy in each state can be found on the PPSG website, at www.medsch.wisc.edu/painpolicy.

Three researchers used a team analysis approach[36] to evaluate guidelines and policy statements that had been adopted in 24 states between 1989 and 1997, the most recent year for which policies were available when this study was begun (see Table 1). Each policy was rated by the three researchers according to several criteria. A determination was made by each rater as to whether the guidelines contained the following items: (1) stated purposes to address concerns about regulatory scrutiny, encourage pain management, and encourage physicians to become knowledgeable about pain management; (2) recognition of the medical use of opioids for pain, including chronic non-cancer pain; and (3) restrictions or requirements that could interfere with

prescribing opioids for pain management.

The raters' evaluations of the items found in each policy were compared to determine the extent of discrepancy, i.e., when raters had different responses. There was an initial agreement of 86% among raters, suggesting high "reproducibility" (p. 17).[37] For each discrepancy, the reasons were determined and a consensus was achieved and recorded on the extent that the items were present in each policy.

Stated Purpose of the Policy. Fifty-four percent of the 24 guidelines (13 states) recognized physicians' concerns about regulatory scrutiny but only 33% (8 states) addressed the concerns by providing guidelines or principles the board uses to distinguish legitimate from questionable prescribing practices. Thirty-eight percent of the guidelines (9 states) actually encouraged pain management, although 45% (11 states) provided physicians with sources of information about pain management, such as the Agency for Health Care Policy and Research clinical practice guidelines or the AAPM/APS consensus statement.

Recognition of Medical Uses for Opioids. Thirty-eight percent of the guidelines (9 states) recognized the use of opioids for cancer pain specifically; 46% (11 states) recognized that opioids may be used for chronic non-cancer pain. Twenty-one percent of the guidelines (5 states) stated the principle that pain management, including the use of opioid analgesics, should be considered a part of quality medical practice.

Additional Requirements and Restrictions. Several board policies placed additional requirements and restrictions on physicians' use of controlled substances for pain. Two states *required* that other treatments be attempted before opioids are used for chronic non-cancer pain. Two state boards asserted that the physician is responsible for knowing if the patient is a drug

abuser; two guidelines appeared to completely restrict physicians from prescribing for patients who use drugs "non-therapeutically" or who have a history of drug abuse.

The evaluation showed a lack of clear and consistent purpose, as well as considerable variation among states.[38] We presented the content analysis results to the FSMB, which had already started looking into ways of improving the content and consistency of state medical board pain policies.

The Development of Model Guidelines for State Medical Boards

In 1997, the FSMB convened a task force of pain, policy and regulatory experts to develop "Model Guidelines for the Use of Controlled Substances for the Treatment of Pain,"[39] which could be given to all state medical boards for their consideration. A draft was prepared, taking advantage of language from several state medical boards' policies that were considered to be models.[40] The FSMB sponsored a public forum to take comments on the draft Model Guidelines from a variety of medical and pain organizations, state medical boards, and patient advocacy groups.[40] A representative of the U.S. Drug Enforcement Administration (DEA) presented a written statement which said in part:

> The guidelines will help physicians comply with acceptable pain management standards and will help DEA and other regulators determine whether such treatment is appropriate under the circumstances. Perhaps most importantly, the guidelines will help ensure patient access to needed controlled substances for pain

management. (p. 4)[41]

The Model Guidelines contain language that clearly recognizes the medical uses of controlled substances for pain, encourages physicians to provide adequate pain management for all patients, recognizes and addresses fear of regulatory scrutiny, and encourages physicians to update their knowledge about pain management (see Table 2).

In addition, the Model Guidelines present clear guidelines for prescribing controlled substances are that based on the general principles of good medical practice. These include a bonafide physician-patient relationship, physical examination, diagnosis, treatment plan, informed consent, periodic monitoring, documentation, consultation as needed, and adherence to federal and state laws concerning controlled substances. The Model Guidelines recognize that opioids may be appropriate for pain control even when a person has a history of substance abuse. Up-to-date definitions are provided for key terms that are commonly misused, including addiction, tolerance and physical dependence. A relatively new concept, "pseudoaddiction,"[42] is also presented in order to draw attention to the need to distinguish between patients who request more pain medications because their pain is inadequately managed, and persons who seek drugs for other than legitimate purposes.

The Model Guidelines do not contain unwarranted additional requirements or restrictions. Indeed, they are intended to be flexible:

> Each case of prescribing for pain will be evaluated on an individual basis. The board will not take disciplinary action against a physician for failing to adhere

strictly to the provisions of these guidelines, if good cause is shown for such deviation. The physician's conduct will be evaluated to a great extent by the treatment outcome, taking into account whether the drug used is medically and/or pharmacologically recognized to be appropriate for the diagnosis, the patient's individual needs – including any improvement in functioning – and recognizing that some types of pain cannot be completely relieved. (p. 4)[39]

The Model Guidelines were unanimously adopted by the Federation's House of Delegates on May 2, 1998. Subsequently, they were endorsed by the APS and the AAPM.[40] The Model Guidelines represent an emerging consensus among groups representing the perspectives of pain management, regulation, and drug law enforcement about the medical use of controlled substances for the treatment of pain. The intention of the FSMB is that the Model Guidelines be considered and acted upon by all state medical boards.[43] The Model Guidelines can be obtained directly from the FSMB website: www.fsmb.org.

Discussion

That physicians fear they will be investigated for writing excessive opioid prescriptions has been described as an "unwritten doctrine" (p. 257).[44] Although opioid analgesics are regarded as the mainstay of treatment for pain related to surgery and trauma for many years, national encouragement of their use for acute and cancer pain did not occur until the mid-1980s.[1-4] Consensus about the use of opioids in chronic non-cancer pain has been lacking,

but has begun to appear.[5,42] With these changes, the advent of new information about pain physiology, opioid pharmacology, and revised conceptions of addiction and dependence, a new body of knowledge is being incorporated into medical education and practice.[45] It is extremely important to ensure that state medical policies adapt to these changes. The Model Guidelines provide a carefully-drafted policy framework that can be considered by state medical boards to accomplish this goal. However, many state medical boards have yet to adopt the new guidelines, as recommended by the FSMB.[43] Since May of 1998, six state medical boards have developed policies that are substantially the same as the Model Guidelines: Alabama, Florida, Kansas, Nebraska, Pennsylvania, and Utah.

Conclusions and Recommendations

Successful elimination of physician fear of regulatory scrutiny will depend in part on achieving more balanced controlled substances policies in each state, policies that aim not only to prevent drug abuse but also acknowledge the important medical uses of controlled substances, in particular the opioid analgesics.[46] It is recognized that it would be an impossible task for medical boards to issue new policies to keep pace with developments in the management of diseases and conditions. However, the Model Guidelines are not clinical practice guidelines; rather, they encourage improved pain management and address physicians fear of regulatory scrutiny, which has been identified as a major barrier to the adequate treatment of pain.

We recommend that all state medical boards consider the reasons for inadequate pain management in the state, adopt guidelines on the use of controlled substances for pain

management, and take other actions to ensure that investigations and discipline are consistent with board policy. New guidelines should be based on the FSMB Model Guidelines and they should be disseminated to physicians, as well as publicized. Medical boards are encouraged to sponsor educational efforts to communicate with physicians and address their perceptions of risk. We urge that medical boards cooperate with state boards of pharmacy and nursing to coordinate and establish policies that reflect a consensus of health-care professionals, as has been done in California, Washington, and North Carolina.

Even though medical boards disseminate guidelines to their licensees, practitioners often remain unaware of new policies in their state.[39,47] The North Carolina medical board has made great effort to disseminate its guidelines, and to sponsor educational programs for both the public and professionals, which is an example of what medical boards can do after they adopt policies. Most medical boards do not have educational resources to do this and will need support. One strategy that has been employed in Alabama is joint sponsorship of educational offerings by the Medical Board and the state medical society. In addition, approximately 75% of medical boards sponsor a website and a newsletter; these are cost-effective and direct ways for boards to communicate with licensed practitioners to inform them of the board's policy to encourage pain management.

If the collective efforts of the pain management and regulatory communities do not make significant progress to eliminate fears of regulatory scrutiny, frustration with physicians who do not provide adequate pain management will mount and may lead to policies that penalize *inadequate* pain management. Such policies have already been discussed by the Institute of Medicine and state medical boards.[22,45] Indeed, a recent action by the Oregon Board of Medical

Examiners resulted in a physician being disciplined because of inadequate pain management.[48] In lieu of license revocation, the Oregon Board required the physician to participate in an intensive educational curriculum about pain management. Education, not discipline, should be the cornerstone of efforts to improve pain management. However, it is axiomatic that, if pain management is an expected part of quality medical practice, then substandard pain management practice must be subject to review and corrective action, as in any other area of medical practice.

The trends in state medical board policies reported here are a reflection of increasing concern about inadequate pain management. Making real improvements in pain management will require the proactive efforts of many organizations. The contribution of state medical boards and other regulatory agencies is a welcome addition.

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References

1. Acute Pain Management Guideline Panel. *Acute Pain Management: Operative or Medical Procedures and Trauma. Clinical Practice Guideline*. AHCPR Pub. No. 92-0032. Rockville, MD: Agency for Health Care Policy and Research, Public Health Service, U.S. Department of Health and Human Services; February 1992.

2. American Pain Society. *Principles of Analgesic Use in the Treatment of Acute Pain and Cancer Pain*. 4th ed. Glenview, IL; 1999.

3. World Health Organization. *Cancer Pain Relief*. Geneva, Switzerland; 1986.

4. Jacox A, Carr DB, Payne R et al. *Management of Cancer Pain. Clinical Practice Guideline*. No. 9. AHCPR Publication No. 94-0592. Rockville, MD: Agency for Health Care Policy and Research, Public Health Service, U.S. Department of Health and Human Services; March 1994.

5. American Academy of Pain Medicine and American Pain Society. *The Use of Opioids for the Treatment of Chronic Pain: A Consensus Statement*. American Academy of Pain Medicine and American Pain Society; 1997.

6. Portenoy RK. Opioid therapy for chronic nonmalignant pain: Clinicians' perspective. *J Law, Med & Ethics*. 1996;24(4):296-309.

7. Bernabei R, Gambassi G, Lapane K, et al. Management of pain in elderly patients with cancer. *JAMA*. 1998;279:1877-1882.

8. Cleeland CS, Gonin R, Hatfield AK, et al. Pain and its treatment in outpatients with metastatic cancer. *N Engl J Med*. 1994;330:592-596.

9. Breitbart W, Rosenfeld BD, Passik SD, McDonald MV, Thaler H, Portenoy RK. The undertreatment of pain in ambulatory AIDS patients. *Pain*. 1996;65(2-3):243-249.

10. Whipple JK, Lewis KS, Quebbeman EJ, et al. Analysis of pain management in critically ill patients. *Pharmacotherapy*. 1995;15(5):592-599.

11. Zhukovsky DS, Gorowski E, Hausdorff J, Napolitano B, Lesser M. Unmet analgesic needs in cancer patients. *J Pain Symptom Manage*. 1995;10(2):113-119.

12. SUPPORT Study Principle Investigators. A controlled trial to improve care for seriously ill hospitalized patients: The study to understand prognoses and preferences for outcomes and risks of treatments (SUPPORT). *JAMA*. 1995;274:1591-1598.

13. Nowels D, Lee JT. Cancer pain management in home hospice settings: a comparison of primary care and oncology physicians. *J Pall Care*. 1999;15(3):5-9.

14. Tanabe P, Buschmann M. A prospective study of ED pain management practices and the patient's perspective. *J Emerg Nursing*. 1999;25(3):171-177.

15. Smith BH, Hopton JL, Chambers WA. Chronic pain in primary care. *Fam Prac*. 1999;16(5):475-482.

16. Ferrell BR, Juarez G, Borneman T. Use of routine and breakthrough analgesia in home care. *Oncol Nurs Forum*. 1999;26(10):1655-1661.

17. Kruger M, McRae K. Pain management in cardiothoracic practice. *Surg Clinics North Amer*. 1999;79(2):387-400.

18. Stevens DS, Edwards WT. Management of pain in intensive care settings. *Surg Clinics North Amer*. 1999;79(2):371-386.

19. Hill CS Jr. The negative effect of regulatory agencies on adequate pain control. *Prim Care Cancer*. 1989;November:45-53.

20. Hill CS Jr. The barriers to adequate pain management with opioid analgesics. *Sem Oncology*. 1993;20(2 Suppl 1):1-5.

21. Joranson DE, Gilson A. Controlled substances, medical practice, and the law. In: Schwartz

HI, ed. *Psychiatric Practice Under Fire: The Influence of Government, the Media, and Special Interests on Somatic Therapies*. Washington, DC: American Psychiatric Press; 1994:173-194.

22. Martino AM. In search of a new ethic for treating patients with chronic pain: What can medical boards do? *J Law, Med & Ethics*. 1998;26(4):332-334.

23. Turk DC, Brody MC, Okifuji EA. Physicians' attitudes and practices regarding the long-term prescribing of opioids for non-cancer pain. *Pain*. 1994; 59:201-208.

24. Von Roenn JH, Cleeland CS, Gonin R., et al. Physician attitudes and practice in cancer pain management: A survey from the Eastern Cooperative Oncology Group. *Annals Intern Med*. 1993;119(2):121-126.

25. McIntosh H. Regulatory barriers take some blame for pain undertreatment. *J Nat Cancer Inst*. 1991;83(17):1202-1204.

26. Weissman DE, Joranson DE, Hopwood MB. Wisconsin physicians' knowledge and attitudes about opioid analgesic regulations. *Wisc Med J*. 1991;December:53-58.

27. Turk DC, Brody MC. What position do APS's physician members take on chronic opioid therapy? *APS Bull*. 1992;2:1-5.

28. Portenoy RK. Therapeutic use of opioids: Prescribing and control issues. In: Cooper JR, Czechowicz DJ, Molinari SP, eds. *Impact of Prescription Drug Diversion Control Systems on Medical Practice and Patient Care.* Division of Clinical Research, National Institute on Drug Abuse. NIDA Research Monograph 131; 1993:35-50.

29. Joranson DE, Gilson AM. Regulatory barriers to pain management *Sem Nursing Onc.* 1998;14(2):158-163.

30. Portenoy RK. Opioid therapy for chronic nonmalignant pain: A review of the critical issues. *J Pain Symptom Manage.* 1996;11(4):203-217.

31. Joranson DE, Cleeland CS, Weissman DE, Gilson AM. Opioids for chronic cancer and non-cancer pain: A survey of state medical board members. *Fed Bull.* 1992;79(4):15-49.

32. Code of Federal Regulations. §1306.07(c).

33. Drug Enforcement Administration. *Physician's Manual: An Informational Outline of the Controlled Substances Act of 1970.* Washington D.C., U.S. Department of Justice; March 1990.

34. Gilson AM, Joranson DE. Controlled substances and pain management: Changing knowledge and attitudes of medical regulators. *J Pain Symptom Manage.* In press.

35. Joranson DE, Gilson AM. State intractable pain policy: Current status. *APS Bull.* 1997;7(2):7-9.

36. Olesen V, Droes N, Hatton D, Chico N, Schatzman L. Analyzing together: recollections of a team approach. In: Bryman A, Burgess RG, eds. *Analyzing Qualitative Data.* New York, NY: Routledge; 1994.

37. Weber RP. *Basic Content Analysis* (Second edition). Newbury Park: Sage Publications; 1990.

38. Monterroso MM, Gilson AM, Williams CM, Nelson JM, Joranson DE. *A Comparison of State Medical Board Pain Guidelines with a National Model.* Poster presented at the 16th annual American Pain Society conference. New Orleans, LA; October 1997.

39. Federation of State Medical Boards of the United States, Inc. *Model Guidelines for the Use of Controlled Substances for the Treatment of Pain.* Euless, TX; May 1998.

40. Joranson DE, Gilson AM. Controlled substances and pain management: A new focus for state medical boards. *Fed Bull.* 1998;85(2):78-83.

41. Good PM. *The Drug Enforcement Administration and Proposed Model Guidelines for the Use of Controlled Substances in Pain Management.* Presentation at the Federation of State

Medical Boards Symposium on Pain Management and State Regulatory Policy. Dallas, TX; March 1998.

42. Weissman DE, Haddox JD. Opioid pseudoaddiction - An iatrogenic syndrome. *Pain*, 36, 363-366, 1989.

43. Federation of State Medical Boards of the United States, Inc. *Position of the Federation of State Medical Boards in Support of Adoption of Pain Management Guidelines*. Euless, TX; February 2000.

44. Weissman DE. Do drug regulations affect medical practice? *J Pain Symptom Manage*. 1992;7:257-258.

45. Institute of Medicine. *Approaching Death: Improving Care at the End of Life*. Washington, D.C.: National Academy Press; 1997.

46. Joranson DE, Gilson AM, Ryan KR, Maurer MA, Nelson JN. *Achieving Balance in State Pain Policy: A Guide to Evaluation, Part I*. Madison, WI: Pain & Policy Studies Group; July 1999.

47. Potter MB, Schafer S, Croughan-Minihane M. *Opioids in the Treatment of Chronic Nonmalignant Pain: The Attitudes and Practices of Primary Care Physicians*. Poster presented

Figure 1 – Legend

The cumulative trend in the number of pain management or controlled substances policies adopted by state medical boards in the United States, 1989-1999.

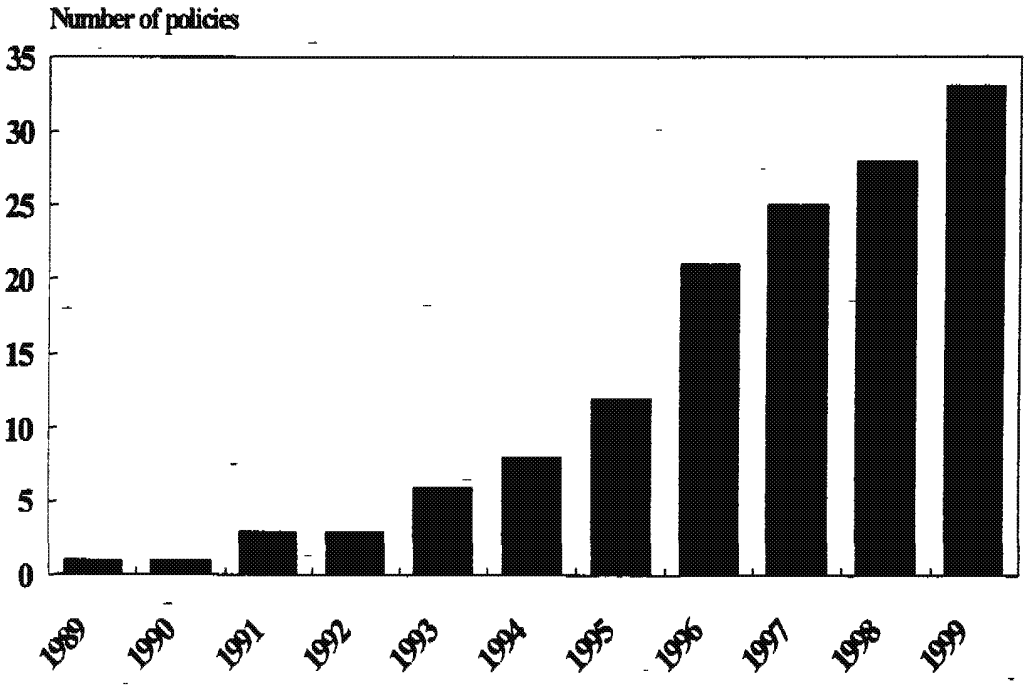

Table 1. – Twenty-four states Represented in Content Evaluation of Medical Board Policies

Alaska	Massachusetts	Rhode Island
Arizona	Minnesota	Tennessee
California	Montana	Texas
Colorado	New Mexico	Utah
Florida	North Carolina	Vermont
Georgia	Ohio	Washington
Idaho	Oklahoma	West Virginia
Maryland	Oregon	Wyoming

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Pharmacists' Knowledge and Attitudes About Opioid Pain Medications in Relation to Federal and State Policy

David E. Joranson[1], MSSW

Director

Aaron M. Gilson[1], Ph.D.

Researcher

[1] Pain & Policy Studies Group; University of Wisconsin-Madison, Comprehensive Cancer Center

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Abstract

Objective: To assess the knowledge and attitudes of Wisconsin pharmacists about the use of opioids in the management of chronic cancer and non-cancer pain, and to explore the potential for these beliefs to interfere with pharmacist dispensing: the last link of the distribution chain of controlled substances to patients.

Design: Mail distribution of self-administered questionnaires. Study period: 1998.

Setting: Urban and rural pharmacies, long-term care facilities, hospitals, and outpatient clinics in Wisconsin.

Patients or Other Participants: Representative sample of Wisconsin pharmacists.

Intervention: None.

Main Outcome Measures: Responses to self-administered questionnaire.

Results: Although most respondents were knowledgeable about the issues addressed in this study, there were important exceptions. Pharmacists did not always know what constitutes legitimate dispensing practices under federal or state policy for situations involving emergencies or for patients with terminal illness, and many were unaware of the important distinction between addiction and physical dependence or tolerance. Many respondents did not view the chronic prescribing/dispensing of opioids for more than several months to patients with chronic pain of

malignant or non-malignant origin as a lawful and acceptable medical practice; this was especially true if the patient had a history of drug abuse.

Conclusion: Pharmacists play a pivotal role in patient access to medications. When viewed in the context of federal and state controlled substances policy, this study suggests that the incorrect knowledge and inappropriate attitudes of some Wisconsin pharmacists could contribute to a failure to dispense opioid analgesics to a patient in pain.

Abstract word count: 243

Introduction

In the United States, inadequate pain relief is prevalent despite the availability of effective pharmacologic and non-pharmacologic treatments.[1-4] Opioid analgesics in the class of morphine are considered safe, effective, and indeed essential for the medical management of acute pain and pain due to cancer.[4-6] In addition, opioids can be effective for other types of pain including sickle cell and for carefully-selected patients with chronic non-cancer pain.[7-9] When appropriate, opioids should be prescribed according to the individual needs of the patient, and must be available when and where they are needed.[1,10] Opioid analgesics are classified as controlled substances due to their potential for abuse. Consequently, they must be prescribed, dispensed, or administered according to federal and state controlled substances laws and regulations.[11-12]

A number of factors contribute to the under-utilization of opioids and to inadequate treatment of pain. These influences include practitioners' lack of knowledge about opioid analgesic pharmacology and effectiveness,[13-19] fear of their effects on respiration,[20-22] fear of their abuse and diversion,[23-26] concern about their addiction liability,[27-32] and concern about regulatory scrutiny from an enforcement or regulatory agency.[12,33-38] The purpose of this article is to examine the potential for pharmacists to be barriers to patient access to opioids for pain management.

The pharmacist is a critical link in the chain of drug distribution to the patient, dispensing drugs such as opioids that are available by prescription only. To dispense opioids, pharmacists must comply with the requirements of federal and state drug, pharmacy, and controlled substances law. Pharmacists are "personal health care advisers" (p. 18) [39] to their patients, but

they are also "gatekeepers" who must determine whether a prescription order is for a legitimate medical purpose and in the usual course of professional practice.[11,40] Pharmacists who lack knowledge about pain management and controlled substances policy could be a weak link if they make decisions that break the chain of legitimate distribution of opioid analgesics to the patient.

A few empirical studies have evaluated pharmacists' beliefs and practices relating to pain management and the regulation of opioids. Early surveys examining attitudes about specific dispensing practices used pharmacies as the sample groups. In 1986, Kanner and Portenoy [29] reported that 29% of pharmacies randomly sampled in New York City did not stock Schedule II opioid analgesics because of a fear of being robbed; only 3% stocked oral morphine. In 1989, Kanner and Cooper [41] surveyed a national sample of pharmacies. Thirty-eight percent of responding pharmacies stocked oral morphine. Those that did not stock oral morphine indicated that the reason was a lack of prescription demand and fear of robbery. The results from these two studies generally mirror those obtained from surveys of pharmacies conducted in other states, such as in New Mexico [42] and South Carolina,[43] and from a recent survey of New York City pharmacies.[44]

Several surveys have evaluated stocking issues, factors that influence dispensing practices, as well as pharmacist knowledge and attitudes about opioid analgesics and the legality of chronic opioid prescribing.[39,45-48] A 1994 survey of North Carolina pharmacists conducted by Krick, Lindley, and Bennett [48] showed that availability of opioid analgesics varied as a function of practice site; pharmacists in community chain or community independent pharmacies generally reported significantly lower availability of opioids than those in hospital pharmacies. While respondents viewed "conservative" physician prescribing (51%) and nurse administration (44%) to be substantial impediments to cancer pain management, 28% considered that both the

risk of addiction and concern about being investigated were important barriers.

A survey of Utah pharmacists [39] revealed deficiencies in pharmacists' knowledge about cancer pain management that could adversely influence a pharmacist's perception of the legitimacy of a prescription order and, therefore, the dispensing of opioids for the treatment of pain. For example, 51% of the respondents believed that the risk of addiction to opioids is high.

One study in New Hampshire is unique because it compares the responses of pharmacists, physicians, and nurses regarding knowledge and attitudes about cancer pain management.[46] Most (88%) of all responding health-care providers viewed the underutilization of opioid analgesics as the primary reason for unrelieved pain. Pharmacists reported that they managed cancer pain more frequently than physicians and nurses. However, pharmacists said that they had inadequate training in cancer pain management and were less comfortable with this role than were physicians and nurses. There was no statistically significant difference between the three professions regarding their perception of addiction risk in cancer patients being treated with opioids. Although the vast majority of physicians (91%), nurses (85%), and pharmacists (86%) believed that addiction was not a clinically relevant phenomenon with cancer patients, it was reported that there were some health-care professionals who thought this was a legitimate concern.

A recent study by Greenwald and Narcessian [47] is the first published survey to assess pharmacists' attitudes about the legality of prescribing of opioids in differing clinical situations. From this small sample of New Jersey pharmacists (n=36), the authors found that only 75% considered the prolonged prescribing for cancer pain to be a lawful and acceptable medical practice. When the cancer pain patient had a history of opioid abuse, only 36% of respondents viewed the prescribing as lawful and acceptable. Pharmacists' confidence in the legal and

medical acceptability of prescribing decreased further when the patient had chronic non-malignant pain (17%) and chronic non-malignant pain with a history of opioid abuse (3%). A majority of responding pharmacists believed that prescribing for these latter two scenarios either should be discouraged or investigated, even though neither of these practices are necessarily illegal or inappropriate.

Survey of Wisconsin Pharmacists

Building on previous research, the purpose of this survey was to assess the knowledge and attitudes of Wisconsin pharmacists about the use of opioids in the management of chronic cancer and non-cancer pain, and to explore the potential for these beliefs to interfere with pharmacist dispensing: the last link of the distribution chain of controlled substances to patients.

Methods

A 51-item questionnaire was developed by the Pain & Policy Studies Group (PPSG), using several questions from previous surveys.[24] The instrument contained questions about demographics, views on dispensing Schedule II opioids, the nature and extent of addiction, abuse, and diversion, judging the validity of prescriptions, perceived effects of legal requirements, knowledge of controlled substances requirements, and the legality of certain prescribing scenarios. The questionnaire was revised after pilot-testing with several practicing pharmacists. The "Wisconsin Pharmacists Survey" was mailed in April, 1998 to a random sample of 1,000 licensed Wisconsin pharmacists obtained from the Wisconsin Department of

Licensing and Regulation. A cover letter stated the subject of the survey, but did not mention specific issues to be examined. The letter also assured respondent confidentiality. Reminder postcards were mailed twice to pharmacists who did not respond to the initial mailing. Responses were tabulated and frequencies and descriptive statistics were calculated for each item. Means are reported as mean±standard deviation.

Results

Sample

One hundred and one surveys were returned either as undeliverable or because the pharmacist was no longer practicing, reducing the overall sample size to 899. A total of 557 questionnaires (62%) were returned, of which 547 were evaluable, for an overall response rate of 61%.

The mean age of the respondent was 45.10±12.01 years (range, 24 to 76 years). Sixty-four percent of the sample were males. Most practicing pharmacists (92%) held a Bachelors of Science degree, while 8% had a graduate degree. Respondents received their pharmacist degrees between 1943 and 1997, with the median year being 1978. The respondents' principle practice settings were chain pharmacies (30%), independent pharmacies (24%), hospitals (22%), and "other" settings (25%). "Other" settings included nursing home or long-term care facilities, outpatient clinics, and outpatient managed-care facilities. Location of the pharmacy practice was city (64%), suburban (19%), and rural (18%). Slightly more than half of the pharmacists (58%) practiced in communities of a population size under 100,000. Approximately two-thirds of pharmacists (62%) were either rarely or not at all involved with hospice care services. Thirty-

three percent of pharmacists were aware that Wisconsin had a Cancer Pain Initiative.

Respondents were asked to rate the adequacy of their undergraduate education about controlled substances requirements and the use of opioids for pain management. Two-thirds rated their education about controlled substances requirements as either Good or Excellent, while 49% viewed their education about opioids and pain management as Good or Excellent.

Views on Addiction, Abuse, and Diversion

Respondents were asked the meaning of "addiction" and were given several characteristics from which to select: Physical dependence, psychological dependence, tolerance, other, and don't know; more than one answer could be chosen. More than three-quarters (79%) viewed "addiction" as some combination of physical dependence, psychological dependence, and tolerance. Eighty-eight percent of pharmacists said that "addiction" means physical dependence, 84% indicated psychological dependence, and 36% chose tolerance. Twelve percent of this sample considered physical dependence alone sufficient to indicate "addiction," and 10% chose psychological dependence only. Less than 1% of pharmacists reported that they did not know what characterized "addiction."

The survey contained an item asking respondents to estimate the approximate incidence of psychological dependence (defined in the questionnaire as "compulsive use for psychic effects") that results from the treatment of pain using opioids. Only 9% viewed its occurrence as an extremely rare event and chose less than one in 1,000; 13% thought the incidence was one in 1,000; 25% chose one in 100; 16% chose one in 10; and nearly 40% did not know.

Almost half of the respondents (46%) said that diversion and abuse of prescription opioid analgesics was a problem in their community, while 33% did not see it as a problem. Of those

respondents who believed that diversion was a problem, 10% (4% of the total sample) said it was serious, 55% (24% of the total sample) thought it was of moderate concern, and 35% (15% of the total sample) indicated it was a minor problem.

Most pharmacists (87%) were confident in their ability to recognize situations where a person attempts to obtain controlled substances from a pharmacy for other than legitimate medical purposes. Thirty-nine percent said this situation was rare and 55% indicated that it happened occasionally. In contrast, two-thirds of pharmacists (68%) were aware of situations where patients with inadequately-treated pain have been suspected by pharmacists to be "drug-seekers" due to their requests for additional pain medications.

Views on Stocking Schedule II Opioids

Half of the respondents (51%) indicated that (in the last two years) they rarely had been unable to dispense a Schedule II opioid analgesic to a patient due to the medication not being in stock. Thirty-five percent stated that this happened occasionally and only 1% reported it as happening often. This situation never happened for 14% of the respondents. The pharmacists were asked to choose from a list the factors those they believed limit the stocking of Schedule II opioid analgesics at their primary practice site. Respondents could choose more than one factor. The most frequently-indicated factor was lack of prescription orders (78%), followed by medication cost (38%), fear of theft or robbery (12%), inadequate reimbursement (8%), fear of pilfering (5%), concern about investigation by a regulatory agency (5%), and potential for drug addiction (2%). In addition, 48% reported that they would not be willing to provide a Schedule II opioid to another pharmacy that temporarily ran out of stock.

Views on Dispensing Schedule II Opioids

Eighty-two percent of pharmacists indicated that they would be willing to dispense a limited quantity of Schedule II opioid medication for a bona fide patient emergency without a written prescription order, on the basis of a prescription order received from a practitioner by telephone. However, 18% said that they would not dispense in this situation. Respondents reported that they would never (4%), occasionally (33%), often (23%), and always (40%) decline to dispense a Schedule II opioid if the original prescription order lacked complete information. When considering the appropriate dosage of an opioid analgesic, 38% of pharmacists somewhat agreed and 9% strongly agreed that a dosage greater than that recommended in the Physicians Desk Reference (PDR) or Product Package Insert is probably excessive and is cause for concern about the appropriateness of a prescription order.

Experience with Controlled Substances Investigations

Fourteen percent of respondents reported having been investigated or audited by a regulatory agency in regard to controlled substances matters. When all respondents were asked to estimate the percent likelihood that they would be audited or investigated by a drug regulatory agency sometime during their career, the mean response was 35±28% (range, 0% to 100%). Seventeen percent agreed to some extent that their records for controlled would not pass scrutiny by a regulatory agency.

Knowledge of Controlled Substances Requirements

These pharmacists were asked if their knowledge of relevant controlled substance regulations was adequate: 53% somewhat agreed and 29% strongly agreed, while 16% somewhat

disagreed and 2% strongly disagreed. Sixty-four percent of respondents knew correctly that federal regulations allow pharmacists to partially dispense a Schedule II opioid analgesic for a terminally ill patient living at home; an equal percentage was aware that this is allowed by state regulations, while 4% somewhat disagreed, 15% strongly disagreed, and 16% did not know. In addition, one-third of respondents (35%) considered that the requirements for prescribing, dispensing, and managing controlled substances had a negative effect on their appropriate medical use.

Perceived Legality of Prescribing/Dispensing Opioids for Chronic Pain

Pharmacists were asked to give their opinion about the legality and medical acceptability of prescribing or dispensing opioids for more than several months in four patient scenarios involving chronic malignant and non-malignant pain, with and without a history of opioid abuse. There were three possible levels of legality for each scenario: (1) lawful and generally acceptable medical practice, (2) lawful but generally not accepted medical practice and should be discouraged, and (3) probably a violation of federal or state controlled substances or medical practice laws and should be investigated. Respondents also were given a "don't know" option. Only one response could be chosen for each scenario. Table 1 contains the frequencies of responses for each chronic pain scenario.

Cancer pain scenarios. Ninety-three percent of the respondents were confident in the legality and medical acceptability of prescribing/dispensing opioids for more than several months for pain patients with a malignancy. If the cancer patient with chronic pain had a history of opioid abuse, confidence decreased to less than two-thirds of the respondents (61%). Seventeen percent would discourage the practice, and 6% would consider the practice as a probable

violation of law. Respondents chose "don't know" most often (16%) for this scenario.

Non-malignant pain scenarios. If the patient's chronic pain is of non-malignant origin, 55% of respondents were confident that prescribing/dispensing opioids for an extended period for such an individual is legal and accepted medical practice. Twenty-nine percent perceived the practice to be legal, but would discourage it. Six percent believed that the practice probably was illegal and should be investigated.

Only 8% of the pharmacists viewed the prescribing/dispensing of opioids for more than several months to a patient with chronic non-malignant pain and a history of opioid abuse as legal and acceptable medical practice. Almost half (46%) of the respondents thought the practice was legal but would discourage it; 34% believed the practice to be in probable violation of controlled substances laws and should be investigated.

Other issues

Respondents were asked their opinion about the effectiveness of marijuana in the treatment of pain. The responses were: Strongly agree (4%), somewhat agree (16%), somewhat disagree (18%), strongly disagree (22%), and don't know (42%).

Discussion

The results of this study should be viewed in the context of federal food and drug and state pharmacy policy, which establishes that going to a pharmacist is the only lawful way for a patient to obtain a prescription-only drug. Controlled substances policies further establish that

the pharmacist has a legal duty not to dispense a controlled substance for other than legitimate medical purposes, which include prescriptions for narcotic drugs for detoxification or maintenance treatment of narcotic addiction, and prescriptions outside the parameters for emergency dispensing and partial filling. However, if a pharmacist does not dispense a valid prescription based on incorrect knowledge or inappropriate attitudes, the last link in the medication distribution chain is broken. Responses to this survey suggest that, while most pharmacists would dispense appropriately, there is a large minority who might not dispense prescriptions due to incorrect knowledge or misconceptions about what is legitimate practice under federal or state policy:

(1) Almost 20% of responding pharmacists would, to some extent, decline to dispense an opioid analgesic during a bona fide patient emergency if the prescription order was received from a practitioner by telephone, although such dispensing is lawful under federal and state policy;[49]

(2) Almost 50% of respondents would consider a dosage of an opioid that is greater than that recommended in the PDR or Product Package Insert to be excessive and cause for concern about its appropriateness. However, federal policy does not restrict a physician's prescribing either to labeled indications or to recommended doses. A physician can prescribe a drug, once it has been approved under the Federal Food, Drug, and Cosmetic (FD&C) Act, in doses and for uses not mentioned in the approved labeling.[50] Indeed, the ability of physicians to prescribe a drug according to their best knowledge and medical judgment is stated in the PDR itself:

> The [Food and Drug Administration] has also recognized that the FD&C Act does not, however, limit the manner in which a physician may use an approved drug...The [Food

and Drug Administration] also observes that accepted medical practice includes drug use that is not reflected in approved drug labeling (p. ii).[51]

(3) Approximately 35% of pharmacists did not know that federal or state regulations allowed them to partially dispense Schedule II opioids for a terminally ill patient living at home, although this practice is authorized in federal policy [52] and in Wisconsin regulations;[53]

(4) Compared to Greenwald and Narcessian's [47] study, Wisconsin pharmacists reported a higher level of confidence in the legality and medical acceptability of prescribing or dispensing opioids from more than several months for all four patient scenarios. Nevertheless, a large minority of Wisconsin pharmacists reported low confidence in the medical and legal acceptability of opioid use in these patient scenarios, even though such prescribing could be within the practice of medicine and, therefore, lawful under federal and state policy to dispense opioid analgesics so long as the purpose remains the treatment of pain.[12,54-55] Beliefs that certain patient characteristics affect the legality of prescriptions for pain have the clear potential to result in decisions to not dispense valid prescriptions.

Diversion of controlled substances

Diversion from pharmacies by criminal acts including robbery is a significant source of prescription controlled substances in the illicit market and a source of drugs that are abused.[56] Twenty-eight percent of the sample believed that diversion of prescription opioid analgesics was a moderate or serious problem in their community. More than half of the respondents reported that attempts to obtain controlled substances from a pharmacy for illicit purposes were at least an occasional occurrence. Finally, one-fourth of this sample reported a theft or robbery in the last

five years. These results suggest that state and federal law enforcement and licensing agencies should review diversion from pharmacies to determine its actual extent. This can be accomplished by a systematic review of data from Drug Enforcement Administration (DEA) Form 106, which pharmacists must complete for all losses of controlled substances. The results of such a review could inform the development of a strategy to apprehend perpetrators of pharmacy crime, and assist pharmacists and pharmacies to prevent diversion.

Pseudoaddiction

These pharmacists also are aware of inadequate pain management, reporting that they were frequently aware of occasions in which patient requests for additional medications due to inadequately-treated pain were misinterpreted by other pharmacists as drug-seeking behaviors related to addiction. Such situations can occur when health-care personnel inappropriately perceive a patient's pain-relief seeking behavior as maladaptive drug-seeking behavior. This is an iatrogenic phenomenon termed "pseudoaddiction."[57] At the same time, these respondents also were confident in their ability to identify attempts to obtain controlled substances for other than legitimate medical purposes. Suspicion that patients are obtaining prescriptions for abuse could lead to a correct decision to not dispense, according to the legal responsibility of the pharmacist not to dispense for other than legitimate medical purposes.[58] It is encouraging that many of these pharmacists do not assume that a patient's efforts to obtain more pain medications invariably are a sign of drug dependence/addiction. The pharmacist can and should play an important role on the health care team by identifying cases of inadequate pain relief and communicating with the patient and care-givers about the need to improve pain management.

Definitions and risk of addiction

Most of these pharmacists' definitions of addiction included *both* physical and psychological dependence, and, to a lesser extent, tolerance. Some pharmacists defined addiction solely on the basis of the manifestation of withdrawal symptoms (i.e., physical dependence), which by itself is insufficient to define addiction/drug dependence (i.e., characterized by a behavioral syndrome).[59-60] Physical dependence is common when opioids are used to manage chronic pain. Consequently, confusion about addiction/drug dependence and physical dependence can lead to an exaggeration of the degree of risk of addiction among patients who are being treated with opioids for chronic pain. Since it is unlawful to dispense opioids for maintenance of narcotic addiction, this confusion could precipitate inappropriate concern about the legitimacy of prescribing and potentially lead to an incorrect decision to not dispense.

When asked to approximate the incidence of psychological dependence resulting from the treatment of pain with opioids, two-thirds of pharmacists (who chose a response other than "don't know") believed that the incidence of psychological dependence occurred in 1% to 10% of all pain patients treated with opioids. This apparent overestimation of the incidence of iatrogenic psychological dependence is a common misperception among health-care practitioners and has been demonstrated in previous studies.[23-24,39,47] Greater effort is needed to provide pharmacists (and other health-care practitioners) with an up-to-date understanding about the characteristics and risk of addiction when opioids are used to treat pain in patients without a history of substance abuse.

Previous surveys have found that concerns about theft or regulatory investigation were a

primary cause for apprehension about stocking and dispensing Schedule II controlled substances. This sample of Wisconsin pharmacists did not identify these as important considerations when deciding to stock such drugs. When a Schedule II opioid analgesics was not stocked, it was reported to be due primarily to a lack of prescription orders and medication cost. In addition, many respondents were reluctant to provide Schedule II opioids to other pharmacies that ran out of stock.

These pharmacists reported a low incidence of being investigated or audited by a state regulatory agency and minimal concern that their pharmacy records would not pass scrutiny if audited. Studies in other states have shown that greater concerns about regulatory investigation and higher fears of theft are associated with the decision not to stock Schedule II controlled substances.[29,41-42,44] This difference may be because Wisconsin discontinued routine pharmacy inspections in favor of a self-inspection program and targeted investigations as needed.

It is interesting to note that although 62% of respondents were not currently involved in hospice care, nearly one-third said that they were aware of the Wisconsin Cancer Pain Initiative. This finding likely reflects the involvement of pharmacists and the state association in the Initiative and publicity about the Initiative in the state pharmacy journal.

Finally, a majority of pharmacists rated their education about controlled substances requirements as either good or excellent, while less than half gave the same rating to their education about pain management. This result is similar to that of Furstenberg et al.,[46] who found that pharmacists were significantly less likely than either physicians or nurses to consider their training in cancer pain management to be adequate or better.

Conclusion

This survey shows that there is a need to further improve Wisconsin pharmacists' understanding about pain management and controlled substances requirements. Most respondents were knowledgeable about the issues addressed in this study. However, there were some major exceptions. This is not surprising, since our knowledge about opioids, pain, and addiction has increased and some policies have changed. Most surveys of health-care professionals about pain and controlled substances policy have similar findings.

Pharmacists did not always know what constitutes legitimate dispensing practices in certain situations (e.g., for emergencies or for patients with terminal illness) according to federal or state policy. Many appeared not to be aware of the important distinction between addiction and physical dependence or tolerance. Many respondents did not view the chronic prescribing/dispensing of opioids for more than several months to patients with chronic pain of malignant or non-malignant origin as a lawful and acceptable medical practice; this was especially true if the patient had a history of drug abuse. If the knowledge and attitudes expressed by these results were translated into practice, there could be a significant risk that some patients would have difficulty getting their prescriptions for opioid analgesics filled.

With the development of new knowledge about pain physiology, opioid pharmacology, and revised definitions of addiction,[10,61] these topics are being incorporated into both medical and nursing education.[1] It would be desirable to review whether pharmacy texts and curriculum have been updated recently regarding these topics. In addition to basic professional education, it is necessary to address the needs of today's pharmacists through continuing education about pain, opioids, the characteristics and risks of addiction, as well as federal and state controlled substances and pharmacy policies, including the more recent changes relating to partial dispensing. Pharmacists, like physicians, should know enough about both pain management and

addiction to be able to distinguish between acceptable and unacceptable practices by today's standards. It may help to develop criteria that would assist pharmacists to evaluate and respond to various dispensing situations that are at risk for incorrect decisions. Such an approach would emphasize a pharmacist's professional responsibility to not dispense invalid prescriptions while dispensing those that are valid. We concur with the standard of decision-making suggested by Brushwood and Carlson to achieve a balance between these two obligations:

> ...regulatory policy should not insist that the uncertainty of a suspicious prescription always be resolved in the most conservative way, by a pharmacist refusing to fill the prescription (p. 483).[58]

In this respect, it is important to note that the DEA has stated that:

> [Controlled substances] have a legitimate clinical use and a practitioner should not hesitate to prescribe, dispense or administer them when they are medically indicated (p. 29).[56]

To further the objective of improving pain management while preventing diversion, we recommend that state pharmacy boards consider adopting guidelines or policy statements that encourage pharmacists to (1) become more involved in pain management, (2) encourage updating knowledge about pain, opioids, addiction, and controlled substances policy, (3) explain the boards' criteria for judging the validity of a particular dispensing practice, and (4) define correctly pain and addiction-related terms such as tolerance, physical dependence, addiction, and

pseudoaddiction. State medical board are at the forefront of issuing new policies to encourage effective pain management,[62-63] with medical boards in 28 states having adopted such policies (see the PPSG website at www.medsch.wisc.edu/painpolicy). To date, only the Pharmacy boards in California and Washington have developed such guidance for pharmacists. We encourage pharmacy boards to undertake this effort in cooperation with the boards of medicine and nursing in their state. This cooperative approach has been undertaken recently in North Carolina, where the boards of medicine, pharmacy, and nursing developed a joint policy statement on pain management and end-of-life care.[64] New guidelines by themselves will have little impact unless they are disseminated to pharmacists and publicized. Finally, we urge pharmacy boards and pharmacy associations to sponsor educational programs about pain management.

Implementation of these recommendations could benefit the public health by reducing diversion and its consequences and costs, and by improving the pharmacist's role as the last link in the distribution chain of pain medications to pain patients.

References

1. Institute of Medicine. *Approaching Death: Improving Care at the End of Life.* Washington, D.C.: National Academy Press; 1997.

2. Jacox A, Carr DB, Payne R, et al. *Management of Cancer Pain. Clinical Practice Guideline.* No. 9. AHCPR Publication No. 94-0592. Rockville, MD: Agency for Health Care Policy and Research, Public Health Service, U.S. Department of Health and Human Services; March 1994.

3. World Health Organization. *Cancer Pain Relief.* Geneva, Switzerland: WHO; 1986.

4. World Health Organization. *Cancer Pain Relief: With a Guide to Opioid Availability.* Geneva, Switzerland: WHO; 1996.

5. Portenoy, RK. Cancer pain: Epidemiology and syndromes. *Cancer.* 1989;63:2298-2307.

6. Portenoy RK. Therapeutic use of opioids: Prescribing and control issues. In: Cooper JR, Czechowicz DJ, Molinari SP, eds. *Impact of Prescription Drug Diversion Control Systems on Medical Practice and Patient Care.* Division of Clinical Research, National Institute on Drug Abuse. NIDA Research Monograph 131; 1993:35-50.

7. Benjamin LJ, Dampier CD, Jacox AK, et al. *Guidelines for the Management of Acute and Chronic Pain in Sickle-Cell Disease.* APS Clinical Practice Guidelines Series, No. 1. Glenview,

IL; 1999.

8. Portenoy RK. Opioid therapy for chronic nonmalignant pain: Clinicians' perspective. *J Law, Med & Ethics*. 1996;24(4):296-309.

9. Portenoy RK. Opioid therapy for chronic nonmalignant pain: A review of the critical issues. *J Pain Symptom Manage*. 1996;11(4):203-217.

10. World Health Organization. *Cancer Pain Relief and Palliative Care: Report of a WHO Expert Committee* (Technical Report Series 804). Geneva, Switzerland: WHO; 1990.

11. Abood RR, Brushwood DB. *Pharmacy Practice and the Law*. 2nd ed. Gaithersburg, MY: Aspen Publishers; 1997.

12. Joranson DE, Gilson A. Controlled substances, medical practice, and the law. In: Schwartz HI, ed. *Psychiatric Practice Under Fire: The Influence of Government, the Media, and Special Interests on Somatic Therapies*. Washington, DC: American Psychiatric Press; 1994:173-194.

13. American Pain Society Quality of Care Committee. Quality improvement guidelines for the treatment of acute pain and cancer pain. *JAMA*. 1995;274:1874-1880.

14. American Pain Society. *Principles of Analgesic Use in the Treatment of Acute Pain and Cancer Pain*. 4th ed. Glenview, IL; 1999.

15. American Academy of Pain Medicine and American Pain Society. *The Use of Opioids for the Treatment of Chronic Pain: A Consensus Statement.* 1997.

16. American Geriatrics Society Panel on Chronic Pain in Older Persons. The management of chronic pain in older persons. *J Amer Ger Soc.* 1998;46:635-651.

17. Bonica JJ. Treatment of cancer pain: Current status and future needs. In: Fields HL, Dubner R, Cervee, F, eds. *Advances in Pain Research and Therapy.* Volume 9. New York, NY: Raven Press; 1985:589-616.

18. Cleeland CS, Cleeland LM, Dar R, Rinehardt LC. Factors influencing physician management of cancer pain. *Cancer.* 1986;58(3):796-800.

19. Ferrell BR, Cronin Nash C, Warfield C. The role of patient-controlled analgesia in the management of cancer pain. *J Pain Symptom Manage.* 1992;7(3):149-154.

20. Alpers A. Criminal act or palliative care? Prosecutions involving the care of the dying. *J Law, Med & Ethics.* 1998;26(4):308-331.

21. Fohr SA. The double effect of pain medication: Separating myth from reality. *J Pall Med.* 1998;1(4):315-328.

22. Sommerville MA. Euthanasia by confusion. *UNSW Law J.* 1997;20(3):550-575.

23. Gilson AM, Joranson DE. Controlled substances and pain management: Changing knowledge and attitudes of medical regulators. *J Pain Symptom Manage.* In press.

24. Joranson DE, Cleeland CS, Weissman DE, Gilson AM. Opioids for chronic cancer and non-cancer pain: A survey of state medical board members. *Fed Bull.* 1992;79(4):15-49.

25. Joranson DE, Ryan KM, Gilson AM, Dahl JL. Trends in the medical use and abuse of opioid analgesics. *JAMA.* 2000;283(13):1710-1714.

26. Lebovits AH, Florence I, Bathina R, et. al. Pain knowledge and attitudes of healthcare providers: Practice characteristic differences. *Clinical J Pain.* 1997;13:237-243.

27. Ward SE, Berry PE, Misiewicz H. Concerns about analgesics among patients and family caregivers in a hospice setting. *Res Nursing Health.* 1996;19:205-211.

28. Paice JA, Toy C, Shott S. Barriers to cancer pain relief: Fear of tolerance and addiction. *J Pain Symptom Manage.* 1998;16:1-9.

29. Kanner RM, Portenoy RK. Unavailability of narcotic analgesics for ambulatory cancer patients in New York City. *J Pain Symptom Manage.* 1986;1:87-89.

30. Lander J. Fallacies and phobias about addiction and pain. *British J Addict.* 1990;85:803-809.

31. McCaffery M. Opioids, addiction, and the terminally ill. *Amer J Nursing*. 1995;95:61-62.

32. McCaffery M, Ferrell BR. Understanding opioids & addiction. *Nursing*. 1994;24:56-59.

33. Haddox JD, Aronoff GM. Commentary: The potential for unintended consequences from public policy shifts in the treatment of pain. *J Law, Med & Ethics*. 1998;26(4):350-352.

34. Hill CS Jr. The barriers to adequate pain management with opioid analgesics. *Sem Oncology*. 1993;20(2 Suppl 1):1-5.

35. Martino AM. In search of a new ethic for treating patients with chronic pain: What can medical boards do? *J Law, Med & Ethics*. 1998;26(4):332-334.

36. Portenoy, RK. Chronic opioid therapy in nonmalignant pain. *J Pain Symptom Manage*. 1990;5(1: Suppl):46-62.

37. Von Roenn JH, Cleeland CS, Gonin R., et al. Physician attitudes and practice in cancer pain management: A survey from the Eastern Cooperative Oncology Group. *Annals Intern Med*. 1993;119(2):121-126.

38. Weissman DE, Joranson DE, Hopwood MB. Wisconsin physicians' knowledge and attitudes about opioid analgesic regulations. *Wisc Med J*. 1991;December:53-58.

39. Doucette WR, Mays-Holland T, Memmott H, Lipman AG. Cancer pain management: Pharmacist knowledge and practices. *J Pharm Care Pain Symptom Control.* 1997; 5(3):17-31.

40. Code of Federal Regulations. Title 21 Part 1306.04(a).

41. Kanner RM, Cooper ES. Availability of narcotic analgesics for ambulatory patients with pain. *Adv Rain Res Ther.* 1989;11:191-195.

42. Holdsworth MT, Raisch DW. Availability of narcotics and pharmacists' attitudes toward narcotic prescriptions for cancer patients. *Annals of Pharmacotherapy.* 1992;26:321-326.

43. Rabon PG, Linette DC, Gonzales MF, et al. Limited availability of medications for cancer patients. *Southern Med J.* 1993;86(8):914-918.

44. Morrison RS, Wallenstein S, Natale DK, et al. "We don't carry that:" Failure of pharmacies in predominantly nonwhite neighborhoods to stock opioid analgesics. *New Eng J Med.* 2000;342(14):1023-1026.

45. Bressler, LR, Geraci MC, Feinberg WJ. Pharmacists' attitudes and dispensing patterns for opioids in cancer pain management. *J Pharm Care in Pain and Symptom Control.* 1995; 3(2):5-18.

46. Furstenberg CT, Ahles TA, Whedon MB, et al. Knowledge and attitudes of health-care

providers toward cancer pain management: A comparison of physicians, nurses, and pharmacists in the State of New Hampshire. *J Pain Symptom Manage*. 1998;15(6):335-349.

47. Greenwald BD, Narcessian EJ. Opioids for managing patients with chronic pain: Community pharmacists' perspectives and concerns. *J Pain Symptom Manage*. 1999;17(5):369-375.

48. Krick SE, Lindley CM, Bennett M. Pharmacy-perceived barriers to cancer pain control: Results of the North Carolina Cancer Pain Initiative pharmacist survey. *Annals of Pharmacotherapy*. 1994;28:857-862.

49. Code of Federal Regulations. Title 21 Part 1306.11(d).

50. Federal Register 2673, 1983.

51. Arky R, et al. *Physicians' Desk Reference*. 53rd ed. Montvale, NJ: Medical Economics Company, Inc; 1999.

52. Code of Federal Regulations. Title 21 Part 1306.13(b).

53. Wisconsin Administrative Code. Pharmacy 8.07(3).

54. Joranson DE, Gilson AM. Policy issues and imperatives in the use of opioids to treat pain in

substance abusers. *J Law, Med & Ethics*. 1994;22(3):215-223.

55. Code of Federal Regulations. Title 21 Part 1306.07(c).

56. Drug Enforcement Administration. *Pharmacist's Manual: An Informational Outline of the Controlled Substances Act of 1970*. Washington D.C.: U.S. Department of Justice; December 1995.

57. Weissman DE, Haddox JD. Opioid pseudoaddiction: An iatrogenic syndrome. *Pain*. 1989;36:363-366.

58. Brushwood DB, Carlson JJ. The pharmacist's responsibility to evaluate suspicious prescriptions. *Food Drug Cosmetic Law J*. 1991;46(3):467-485.

59. World Health Organization. *The ICD-10 Classification of Mental and Behavioural Disorders: Clinical Descriptions and Diagnostic Guidelines*. Geneva, Switzerland: WHO; 1992.

60. American Psychiatric Association. *Diagnostic and Statistical Manual of Mental Disorders*. 4th ed. Washington, DC: APA; 1994.

61. Joranson DE. Current thoughts on opioid analgesics and addiction. *Symptom Cont Cancer Pat (Japan)*. 1995;6(1):105-110.

62. Joranson DE, Gilson AM. Improving pain management through policy making and education for medical regulators. *J Law, Med & Ethics*. 1996;24(4):344-347.

63. Joranson DE, Gilson AM. State medical boards, controlled substances, and pain management: A decade of change. *JAMA*. Submitted for publication.

64. North Carolina Medical, Nursing, and Pharmacy Boards. *Joint Statement on Pain Management in End-of-Life Care*. Raleigh, NC; October 21, 1999.

Table 1. – Legality and Medical Acceptability of Extended Opioid Prescribing/Dispensing

	Level of Perceived Legality			
	Lawful and generally acceptable medical practice, with no need to investigate	Lawful and generally not acceptable medical practice which should be discouraged	Violation of medical practice laws and regulations which should be investigated	Violations of controlled substances laws which should be investigated
Cancer pain	93%	1%	2%	7%
Cancer pain with history of opioid abuse	61%	17%	6%	16%
Chronic non-cancer pain	55%	29%	6%	6%
Chronic non-cancer pain with history of opioid abuse	8%	46%	34%	9%

Note: Rows do not sum to 100% due to rounding error.

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Controlled Substances and Pain Management: Changes in Knowledge and Attitudes of State Medical Regulators

Aaron M. Gilson, Ph.D.; David E. Joranson, MSSW

Pain & Policy Studies Group, Comprehensive Cancer Center, University of Wisconsin, Madison, Wisconsin, USA

Address correspondence to:

Aaron M. Gilson, Ph.D.

Pain & Policy Studies Group

University of Wisconsin - Madison

1900 University Avenue

Madison, WI 53705

Tel: (608)263-7662

Fax: (608)263-0259

amgilson@facstaff.wisc.edu

Abstract

Physicians report that concern about regulatory investigation influences negatively their prescribing of opioid analgesics. The views of medical regulators about the legality of prescribing controlled substances for pain management were studied in 1991. However, little is known about whether these views have changed in light of increased emphasis on pain management and educational programs for state medical boards. Two studies are described that examined this issue. In Study 1, a 1997 survey of state medical board members was compared to results obtained in 1991 to evaluate differences in knowledge and perceptions about opioid analgesics. Important changes were observed over time, particularly regarding characteristics of "addiction" and the legality of prolonged opioid prescribing. For Study 2, a longitudinal survey was conducted of medical board members who participated in five workshops about pain management and regulatory policy. Results revealed significant and sustained changes in attitudes about the incidence of iatrogenic addiction when using opioids to treat pain, the analgesic and side-effect properties of opioids, and the perceived legality of opioid prescribing. Recommendations for decreasing concerns about regulatory scrutiny are presented, including the need for a more intensive education program, increasing the rate of adoption of new state medical board policies, and increasing communication between regulators and clinicians.

Key Words

Medical boards, pain policy, chronic pain, cancer pain, opioids

Running Title

Knowledge and Attitudes of Medical Regulators

Introduction

In the U.S., inadequate relief of pain is prevalent.[1-3] Although there are many effective pharmacological and non-pharmacologic pain treatments available, opioids are essential for the medical management of moderate to severe acute pain[4] and pain due to cancer.[1,5,6] There is also a consensus of pain medicine and regulatory experts that opioids are appropriate for selected patients with chronic non cancer pain.[7-10]

Opioids are controlled substances and are subject to additional requirements for prescribing.[11] Their status as controlled substances, however, is not intended to affect their legitimate medical use.[12] Prescribing of opioid analgesics for pain is a legitimate medical practice if done in the course of professional practice, and has been recognized as such by regulatory and legislative groups.[13-17] Prescribing opioids for pain patients with a history of or current substance abuse is also a legitimate medical practice, as long as the purpose of prescribing is for pain, and not for the treatment of narcotic addiction. The prescribing of opioids (narcotic drugs) for the treatment of addiction is not a legitimate medical practice, unless the practitioner is registered as a Narcotic Treatment Program to dispense (but not prescribe) approved drugs such as methadone according to strict federal and state regulations.[18] The long history of the regulation of opioids as controlled substances, the further regulation of their use for the treatment of "narcotic addiction," and misunderstanding of addiction has contributed to confusion about the legality of prescribing under various circumstances.[19,20]

Physicians' concern about being investigated by controlled substances agencies or state medical boards for prescribing "excessive" amounts or for the wrong patients can negatively affect prescribing practices.[11,21-27] Although there is little evidence to support a high risk of

regulatory sanction for prescribing opioid analgesics legitimately for pain,[24,28] physician fears of disciplinary action and criminal prosecution are reinforced by national media coverage of a small number of investigations of doctors for excessive prescribing.[29-31] Concern about prescribing opioids exists among physicians in general practice, but also among oncologists[32] and pain specialists.[33]

A study in 1991 examined the question of whether physicians are justified in their concern about regulatory oversight.[34] A survey was used to evaluate state medical board members' knowledge and attitudes about the medical use of opioids for chronic cancer and non-cancer pain. The results showed that medical board members often defined "addiction" to include "physical dependence" or "tolerance," which are common in chronic pain patients treated with opioids. Neither physical dependence nor tolerance are sufficient to define addiction.[1,5,7] Confusion of physical dependence or tolerance with addiction raises the possibility that a physician's opioid prescriptions for a chronic pain patient could be viewed as questionable medical practice, if not illegal. Indeed, the 1991 survey showed that many board members did not accept the extended prescribing of opioid analgesics to treat chronic pain, especially chronic non-cancer pain; many would discourage or even investigate this practice as a violation of law. If the pain patient had a history of substance abuse, nearly all medical board members would discourage or investigate opioid prescribing, even though such prescribing -- if for pain -- would be legal. These results suggested there could indeed be a risk of regulatory investigation or discipline to physicians who prescribe opioids even when for the legitimate medical purpose of treating pain.

Results of the survey of board members were presented to the Federation of State Medical

Boards of the U.S. (FSMB). Discussions led to the development of a series of educational workshops about the use of controlled substances for pain management, entitled "Pain Management in a Regulated Environment." A total of 11 workshops were held between 1994 and 1998 and were designed in cooperation with the FSMB. Faculty members for the workshops represented the American Pain Society (APS), the American Academy of Pain Medicine, the American Society of Addiction Medicine, and the University of Wisconsin Pain & Policy Studies Group (PPSG). The workshop curriculum addressed opioid pharmacology, pain management, addiction, as well as trends and issues in federal and state policies relating to the use of controlled substances for pain. Both the curriculum and faculty were substantially the same for all 11 workshops. The format of the workshop also allowed discussion of regulatory and clinical practice topics of interest to the participants. Overall, 25% of the total U.S. board member population participated in the workshops, representing 40 state medical boards.

Between 1994 and 1998 there was an increase in the number of pain policies adopted by state medical boards. Some of these policies encouraged better treatment of pain for patients with chronic cancer and non cancer pain, and addressed physicians' concern about regulatory scrutiny.[35] During this period, there also were national consensus statements about the use of opioids in chronic pain,[1,9] state pain study commissions and task forces,[36] as well as new intractable pain treatment statutes and regulations.[37]

In light of this educational and policy activity, two studies were designed to determine whether the views of state medical regulators about the long-term use of opioid analgesics had changed. In Study 1, we re-surveyed all state medical board members in 1997 to evaluate any changes in knowledge and attitudes since 1991. In Study 2, we evaluated whether changes

occurred in a different group of medical board members who participated in the five educational workshops about pain management that were held in 1998. Pre-test, post-test, and follow-up surveys were given to all participants to assess changes in their knowledge and attitudes about opioid analgesics and the legitimacy of prescribing such drugs for pain.

Study 1: Re-Survey of State Medical Board Members

Two specific aims guided analyses of the 1997 re-survey of medical board members. First, responses from the 1997 sample of medical board members were compared to those from the 1991 sample. Second, respondents from the 1997 sample who had participated in the six pain management workshops held between 1994 and 1996 were compared to those who had not participated. The purpose of this analysis was to determine any changes in knowledge and attitudes that might be due to participation in the workshops.

Methods

Instrumentation

The 1997 study used a self-report questionnaire consisting of 34 pre-tested items about clinical and policy issues related to pain. The items included those from the 1991 survey,[34] as well as six items to evaluate new topics of interest. The results presented in this article address respondents' perceptions in four major areas: (1) cancer pain and its treatment, (2) nature and extent of opioid analgesic addiction, abuse, and diversion, (3) medical board policies and legal impediments to pain management, and (4) legality of prolonged opioid prescribing in several different patient scenarios.

Results

Specific Aim I: Comparison of Respondents from the 1991 and 1997 Surveys

Sample

Due to the national turn-over rate of board members, only 6% of the 1997 respondents (n=20) had participated in the 1991 survey. The results presented here, therefore, reflect changes in the knowledge and perceptions of two different groups of board members.

Demographic characteristics of the 1997 board members, as well as for those surveyed in 1991, are shown in Table 1. The two samples are quite similar. Mean age of the respondents in 1997 was 56 years (range, 34-81 years). Length of service on a state board ranged from one year to 25 years and represented a mean of 5 years. The vast majority of board members were physicians. Sixteen percent of the respondents were public members and 4% were other health professionals. Thirteen percent of the sample were members of a state osteopathic board. Physician respondents received their medical degrees between 1943 and 1991; their median year of graduation was 1966. This was the only demographic variable that was statistically significant between the 1991 and 1997 samples ($MW(535) = -5.276$, $p<.0001$), and is merely a reflection of the six-year difference between survey time-frames.

Cancer pain and its treatment

Board members surveyed in the 1997 sample were more likely than those in 1991 to understand the extent to which cancer pain relief is possible. Board members in 1997 believed

that significantly more cancer-related pain could be relieved using available therapies, including opioid analgesics (MW(650) = -3.396, p<.001). More respondents in 1997 viewed the majority of cancer pain patients in their state as "undermedicated" ($\chi^2(2) = 11.146$, p<.005). Thus, medical regulators were more likely in 1997 than in 1991 to recognize that opioids are underutilized as analgesics for cancer pain.

Addiction, abuse, and diversion

There were no differences in responses between 1997 and 1991 regarding the approximate incidence of psychological dependence ("addiction") or about the extent that diversion and abuse of prescription opioids was a problem in their community. Most respondents in both surveys overestimated the incidence of addiction and considered diversion to be a minor to moderate problem. The only statistically significant difference between samples involved board members' knowledge about the meaning of "addiction." Board members were asked to define addiction using a brief list of several common terms, such as "physical dependence," "psychological dependence," "tolerance," or a combination of terms. In 1997, fewer respondents associated addiction solely with physical dependence ($\chi^2(1) = 9.558$, p<.005). Conversely, there was a much greater likelihood in 1997 for board members to define addiction as psychological dependence alone ($\chi^2(1) = 28.669$, p<.001).

Policy awareness

Respondents surveyed in 1997 reported more often that their state medical board has a policy or guideline for the appropriate prescribing of opioid analgesics for pain management

($\chi^2(1) = 25.003$, $p<.001$). This result reflects the increase in the number of pain policies that were adopted by state medical boards between 1991 and 1997.[35]

Legality of opioid prescribing

Board members were asked to judge the legality of prescribing opioids for more than several months in four different patient scenarios: (1) chronic cancer pain, (2) chronic cancer pain with a history of opioid abuse, (3) chronic non-cancer pain, and (4) chronic non-cancer pain with a history of opioid abuse. The response options were that the practice was: (1) Lawful and generally acceptable medical practice, (2) Lawful but generally not acceptable and should be discouraged, (3) Probably a violation of state medical laws or regulations and should be investigated, and (4) Probably a violation of federal or state controlled substances laws and should be investigated. More than one response could be chosen by individuals who believed that both categories of illegality were applicable. Table 2 contains the frequencies of responses within each chronic pain scenario for 1991 and 1997.

Cancer pain scenarios. Compared to respondents in 1991, those in 1997 viewed the prescribing of opioids for more than several months for cancer pain as both lawful and acceptable medical practice ($\chi^2(2) = 17.060$, $p<.001$). Likewise, when the cancer patient also had a history of opioid abuse, medical board members surveyed in 1997 were more likely than those in 1991 to view opioid prescribing as lawful and generally acceptable ($\chi^2(2) = 15.225$, $p<.001$).

Non-cancer pain scenarios. Compared to the two cancer-related scenarios, medical board members were generally much more skeptical about prescribing opioids for non-cancer pain.

Respondents in 1997 were more likely than in 1991 to consider prescribing to patients with chronic non-cancer pain for more than several months as acceptable medical practice ($\chi^2(2) = 61.978$, $p<.001$). These regulators viewed the prolonged prescribing of opioids to a patient with chronic non-cancer pain and a history of drug abuse as least acceptable. However, medical board members in 1997 were more likely to view such prescribing as a lawful and acceptable medical practice ($\chi^2(2) = 36.211$, $p<.001$). Although statistically significant, it should be noted that only 6% of the 1997 sample gave this response.

Specific Aim II: Analysis of Workshop Participants

Twelve percent (n=41) of the 1997 board members reported that they had participated in one of the six workshops on pain management held between 1994 and 1996. This subsample was large enough to compare the responses of participants and non-participants on a limited set of survey items. To preserve the statistical power of the analyses, only those items were analyzed that relate to the legality of prescribing opioids for pain.

There were no statistically significant differences in responses to the cancer pain scenarios between 1991 and 1997. Indeed, a majority of board members were confident in the legal and medical acceptability of this practice. However, board members who attended workshops were more likely than those who didn't to view opioid prescribing for non-cancer pain as lawful and generally accepted medical practice ($\chi^2(2) = 7.362$, $p<.05$). This was also true for the scenario involving non-cancer pain and a history of opioid abuse ($\chi^2(2) = 11.503$, $p<.005$). Since there is generally a greater reluctance to view prescribing for patients with non-cancer pain or a history of drug abuse as legitimate, it is encouraging that participation in the education

program was associated with increased acceptance of this practice.

Study 2: Prospective Survey of Workshop Participants

Study 2 was a longitudinal assessment of the effects of workshop attendance on knowledge and attitudes among medical board regulators who participated in any of the five workshops held in 1998.

Methods

Instrumentation

The evaluation was conducted using a 31 item self-report questionnaire. Most of the items addressed the workshop content and a few were adapted from the 1991 and 1997 surveys of medical board members.[34] The survey addressed: (1) cancer pain and its treatment, (2) addiction issues, (3) analgesic and side-effects of opioids, and (4) perceived legality of prolonged opioid prescribing in several different patient scenarios. Each participant completed the survey three times: Before the workshop (pre-test), immediately after its completion (post-test), and after approximately six months (follow-up).

Sample

The sample for this study was all participants in five regional medical board workshops co-sponsored by the PPSG and the FSMB in 1998. Curriculum and the faculty were similar for each workshop, and addressed the nature and extent of pain, the barriers to adequate relief, both pharmacologic and non-pharmacologic treatments for pain, the appropriate medical use of

opioids, definition and prevalence of addiction, and the current status of pain management and controlled substances policies.

Statistical Analysis

All data were analyzed using non-parametric methods at a .05 significance level. Chi-Square tests were used to evaluate whether workshop participation was significantly associated with the categorical survey items. The effect of the time of assessment (i.e., pre-test, post-test, and follow-up) on any continuous dependent variable was calculated using the Wilcoxon matched-pair signed-rank test. This method of statistical analysis typically identifies changes that are significant using the pre-test as the point for comparison.

Results

Sample

Seventy workshop participants were surveyed at pre-test. Age of the participants ranged from 28 to 83, with a mean age of 54 years (SD=10.32). Males represented slightly more than half (57%) of the sample. The workshop audience consisted of physician members (49%), investigators (10%), executive directors or secretaries (9%), attorneys (9%), public members (7%), and "other" board members (16%). Length of service on the board ranged from one year to 21 years, with a mean of 5 years. Physician members reported that they had received their medical degrees between 1952 and 1984, with a median of 1964. A large majority of physician respondents (87%) were currently practicing medicine.

As expected with any longitudinal study design, sample attrition occurred at follow-up

assessment, decreasing 36% from pre-test to follow-up, with 45 respondents submitting a completed survey after six months. Loss of participants can lead to sample bias if the final sample varies considerably from the initial group of respondents. Demographic characteristics of the pre-test and follow-up samples were, therefore, compared to determine the extent of dissimilarity. If sample differences are found at the time of the follow-up survey, changes in responses across time can result from such differences rather than from workshop participation. There were no statistically significant differences between the pre-test and follow-up samples on any demographic characteristic.

Cancer pain and its treatment

Workshop participants were more likely both at post-test (Wilcoxon(61) = 2.895, $p<.005$) and follow-up (Wilcoxon(36) = 3.737, $p<.001$) to believe that available therapies, including opioid analgesics, can relieve cancer pain effectively. In addition, board members were less familiar at pre-test about the degree to which patients under-report pain ($\chi^2(8) = 17.461$, $p<.05$).[a] It appears that the workshops increased participant awareness of the potential for patients to under-report pain.

Addiction

At pre-test, medical regulators viewed addiction as a frequent occurrence when opioids

[a] A significant chi-square result indicated variability in responses given by the same individual at pre-test, post-test, and follow-up. Adjusted standardized residuals were then used to identify the patterns in the data that contributed to the statistical significance. In all instances of statistical significance, the largest residual was found at pre-test (i.e, pre-test was the reference category). As a result, significant chi-square associations are interpreted in terms of different responses being given at pre-test, as compared to post-test and follow-up.

are used for a prolonged period of time ($\chi^2(8) = 31.548$, $p<.001$), and defined addiction as physical dependence ($\chi^2(8) = 29.144$, $p<.001$). Since these beliefs were significantly less prevalent after participating in the workshop, the survey results suggest that the workshop was successful in clarifying the definition of addiction.

Analgesic and side-effect properties of opioids

Medical regulators were less likely to understand the pharmacodynamics of opioid analgesics prior to the workshop. Respondents were less likely to know at pre-test whether prolonged opioid use leads to a deterioration of organ functioning ($\chi^2(6) = 29.493$, $p<.001$) or to a decrease in cognitive function ($\chi^2(8) = 26.612$, $p<.001$). Before the workshop, participants also were more likely to believe that there is a ceiling to the analgesic effect of morphine ($\chi^2(8) = 51.309$, $p<.001$), and that tolerance diminished the analgesic efficacy of opioids ($\chi^2(8) = 42.673$, $p<.001$). In general, there was a greater likelihood of inaccurate knowledge about the effects of opioids prior to the workshop.

Legality of prolonged prescribing

Cancer pain scenarios. Compared to responses given at both post-test and follow-up, respondents at pre-test were less likely to view the prolonged prescribing of opioids for cancer pain as a lawful and accepted medical practice ($\chi^2(6) = 18.701$, $p<.005$). Likewise, when the cancer patient also had a history of opioid abuse, a lower proportion of regulators surveyed at pre-test viewed opioid prescribing as lawful and generally accepted ($\chi^2(6) = 16.732$, $p<.01$).

Non-cancer pain scenarios. The findings for both the non-cancer pain scenarios were

similar to those obtained for the two cancer pain scenarios. Prior to workshop participation, respondents were less likely to consider as legal and acceptable medical practice the long-term prescribing of opioids to patients with chronic pain not due to cancer ($\chi^2(6) = 25.467$, $p<.001$), as well as chronic non-cancer pain with a history of substance abuse ($\chi^2(6) = 20.577$, $p<.005$).

Discussion

Study 1, the second survey of state medical board members, revealed that there had been important, although not profound, improvements in knowledge, attitudes, and beliefs since 1991. In 1997, board members were more likely to recognize the efficacy of opioid analgesics for cancer pain, but that cancer pain patients are not adequately treated for pain. In addition, board members in 1997 had greater confidence in all four scenarios that prescribing opioids of chronic pain was legal and accepted medical practice. Although still representing a small percentage of the total sample, more board members in 1997 viewed the prescribing of opioids to be lawful and medically acceptable for the treatment of chronic non-cancer pain, as well as for those with chronic pain and a history of opioid abuse. This difference between the two samples represents encouraging movement toward recognizing the legitimacy of prescribing that, by today's standards, would be considered acceptable medical practice.[10]

The data also suggest a positive shift in medical board members' understanding of what addiction is and is not. Fewer participants in 1997 defined it solely on the basis of the manifestation of a withdrawal syndrome. This represents encouraging movement toward the use of behavioral, rather than physiological, measures of addiction. Nevertheless, physiological interpretations of addiction remain common. A much more concerted effort is needed to bring

significant changes in knowledge and attitudes were observed over time and as a result of involvement in an educational workshop, most medical board members continued to view the prolonged prescribing of opioid analgesics for chronic pain as inappropriate medical practice to be discouraged or even investigated. In addition, there continues to be confusion about the characteristics of addiction and about the approximate incidence of iatrogenic addiction. If there is confusion among regulators about addiction, there is the potential for investigating physicians for prescribing practices that may conform to present standards.

Improving pain management in America will depend, in part, on a three-part program that includes: (1) more intensive educational programs for state medical board members and staff, (2) accelerated policy development by state medical boards to encourage pain management and address concerns about regulatory scrutiny, and (3) increased communication between clinicians and their regulators.

(1) Education. State medical boards should sponsor educational efforts for their members, staff, investigators, and attorneys to update their knowledge and views about pain management and regulatory policy. An excellent example is provided by the medical boards in Alabama and North Carolina; they held educational workshops to inform their members and staff.[38] After the workshops, these boards adopted guidelines to recognize the use of controlled substances for the treatment of chronic pain.[17,38]

(2) Policy. State medical boards should adopt or amend[b] their existing guidelines according to the national standard established by the FSMB, "Model Guidelines for the Use of

[b] It is recognized that many state medical boards have already adopted guidelines; however, some of these policies fail to encourage pain management or address directly licenses concerns about regulatory scrutiny.

Controlled Substances for the Treatment of Pain."[10] The Model Guidelines offer significant advantages over current state medical board policies.[17,19] The Model Guidelines address directly physician concern about investigation or discipline:

> Physicians should not fear disciplinary action from the Board or other state regulatory or enforcement agency for prescribing, dispensing, or administering controlled substances, including opioid analgesics, for a legitimate medical purpose and in the usual course of professional practice. (p. 2)[10]

Indeed, the Model Guidelines are an unprecedented consensus among groups that represent pain management, regulatory, and drug law enforcement about the medical use of controlled substances for the treatment of pain.[17]

(3) Communication. Once a state medical board has updated its views about pain management and has adopted or adapted[c] the Model Guideline, it should disseminate and publicize the policy widely and repeatedly to encourage positive practice change and reduce concerns about regulatory scrutiny.[10,17,21] Despite initial dissemination efforts by medical boards, practitioners may be unaware of the board's policy.[17,39] The North Carolina Medical Board (NCMB) provides an example of what state boards can do: In addition to systematic dissemination of its guidelines, the NCMB sponsored educational programs and media events for health-care professionals and for the public.[38]

We should not be surprised that knowledge and attitudes are slow to change. However,

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[c] It is recognized that state policies may differ and that boards may adapt and improve on the Model Guidelines.

these studies show that change is indeed occurring. We can accelerate the rate of change with more concentrated efforts. Increasingly, state medical boards and their members and staff are coming to recognize that pain control is a significant health-care problem, and that they have an important role to play in eliminating fears of regulatory scrutiny. Making this a reality will require additional efforts and further cooperation between medical boards and the pain management community.

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References

1. Jacox A, Carr DB, Payne R et al. Management of cancer pain. Clinical Practice Guideline. No. 9. AHCPR Publication No. 94-0592. Rockville, MD: Agency for Health Care Policy and Research, Public Health Service, U.S. Department of Health and Human Services, March 1994.

2. Institute of Medicine. Approaching death: improving care at the end of life. Washington, D.C.: National Academy Press, 1997.

3. SUPPORT Study Principle Investigators. A controlled trial to improve care for seriously ill hospitalized patients: the study to understand prognoses and preferences for outcomes and risks of treatments (SUPPORT). J Amer Med Assoc 1995;274:1591-1598.

4. Acute Pain Management Guideline Panel. Acute pain management: operative or medical procedures and trauma. Clinical Practice Guideline. AHCPR Pub. No. 92-0032. Rockville, MD: Agency for Health Care Policy and Research, Public Health Service, U.S. Department of Health and Human Services, February 1992.

5. World Health Organization. Cancer pain relief with a guide to opioid availability. Geneva, Switzerland, 1996.

6. World Health Organization. The use of essential drugs: report of a WHO expert committee (Technical Report Series 882). Geneva, Switzerland: WHO, 1998.

7. Savage SR. Opioid use in the management of chronic pain. Med Clinics of North Amer 1999;83(3):761-786.

8. Portenoy RK. Opioid therapy for chronic nonmalignant pain: clinicians' perspective. J Law, Med & Ethics 1996;24(4):296-309.

9. American Academy of Pain Medicine and American Pain Society. The use of opioids for the treatment of chronic pain: A consensus statement. American Academy of Pain Medicine and American Pain Society, 1997.

10. Federation of State Medical Boards of the United States, Inc. Model guidelines for the use of controlled substances for the treatment of pain. Euless, TX, May 1998.

11. Joranson DE, Gilson AM. Controlled substances, medical practice, and the law. In: Schwartz HI, ed. Psychiatric practice under fire: the influence of government, the media, and special interests on somatic therapies. Washington, DC: American Psychiatric Press,1994:173-194.

12. Controlled Substances Act of 1970. Pub L No 91-513, 84 Stat 1242.

13. Code of Federal Regulations. Title 21 Part 1306.04-1306.12.

14. Drug Enforcement Administration. Physician's manual: an informational outline of the Controlled Substances Act of 1970. Department of Justice, Drug Enforcement Administration, 1990.

15. National Conference of Commissioners on Uniform State Laws. Uniform Controlled Substances Act. Chicago, IL: NCCUSL, July 29-August 5, 1994.

16. Joranson DE, Gilson AM. Regulatory barriers to pain management. Sem Nursing Onc 1998;14(2):158-163.

17. Joranson DE, Gilson AM. Controlled substances and pain management: A new focus for state medical boards. Fed Bull 1998;85(2):78-83.

18. Joranson DE. Is methadone maintenance the last resort for some chronic pain patients? Amer Pain Soc Bull 1997;7(5):1, 4-5.

19. Joranson DE, Gilson AM, Dahl JL, Haddox JD. State medical boards, controlled substances, and pain management: a decade of change. J Amer Med Assoc submitted for publication.

20. Weissman DE. Doctors, opioids, and the law: the effect of controlled substances regulations on cancer pain management. Sem Onc 1993;20(1):53-57.

21. Haddox JD, Aronoff GM. Commentary: the potential for unintended consequences from public policy shifts in the treatment of pain. J Law, Med & Ethics 1998;26(4):350-352.

22. Hill CS Jr. The negative effect of regulatory agencies on adequate pain control. Prim Care Cancer 1989;November:45-53.

23. Hill CS Jr. The barriers to adequate pain management with opioid analgesics. Sem Onc 1993;20(2 Suppl 1):1-5.

24. Martino AM. In search of a new ethic for treating patients with chronic pain: what can medical boards do? J Law, Med & Ethics 1998;26(4):332-334.

25. Weissman DE, Joranson DE, Hopwood MB. Wisconsin physicians' knowledge and attitudes about opioid analgesic regulations. Wisc Med J 1991;December:53-58.

26. Turk DC, Brody MC, Okifuji EA. Physicians' attitudes and practices regarding the long-term prescribing of opioids for non-cancer pain. Pain 1994;59:201-208.

27. Portenoy RK. Opioid therapy for chronic nonmalignant pain: current status. In: Fields HL,

Liebeskind JC, eds. Progress in pain research and management, Volume 1. Seattle, WA: IASP Press, 1994:247-287.

28. Johnson SH. Disciplinary actions and pain relief: analysis of the Pain Relief Act. J Law, Med & Ethics 1996;24(4):319-327.

29. McIntosh H. Regulatory barriers take some blame for pain undertreatment. J Nat Cancer Inst. 1991;83(17):1202-1204.

30. In the Matter of DiLeo. 661 So. 2d 162 (La. Appl. 1995).

31. Hoover v. Agency for Health Care Administration. 676 So. 2d 1380 (Fla. Dist. Ct. App. 1996).

32. Von Roenn JH, Cleeland CS, Gonin R., et al. Physician attitudes and practice in cancer pain management: a survey from the Eastern Cooperative Oncology Group. Annals Intern Med 1993;119(2):121-126.

33. Turk DC, Brody MC. What position do APS's physician members take on chronic opioid therapy? Amer Pain Soc Bull 1992;2:1-5.

34. Joranson DE, Cleeland CS, Weissman DE, Gilson AM. Opioids for chronic cancer and non-

cancer pain: a survey of state medical board members. Fed Bull 1992;79(4):15-49

35. Joranson DE, Gilson AM. State intractable pain policy: current status. Amer Pain Soc Bull 1997;7(2):7-9.

36. Joranson DE. State pain commissions: new vehicles for progress? Amer Pain Soc Bull 1996;6(1):7-9.

37. Joranson DE. Intractable pain treatment laws and regulations. Amer Pain Soc Bull 1995;5(2):1-3,15-17.

38. Joranson DE, Gilson AM. Improving pain management through policy making and education for medical regulators. J Law, Med & Ethics 1996;24(4):344-347.

39. Potter MB, Schafer S, Croughan-Minihane M. Opioids in the treatment of chronic nonmalignant pain: the attitudes and practices of primary care physicians. Poster presented at the 17th annual American Pain Society conference, San Diego, CA: November 1998.

Table 1. Demographic Characteristics of Survey Respondents

Characteristics	Year of Survey			
	No. of		No. of	
	1991		1997	
Full sample	surveys	%	surveys	%
	(N=304)		(N=368)	
Age in years				
Mean	55.22		55.67	
Standard Deviation	10.93		10.62	
Board type				
Medical	269	88.5	322	86.8
Osteopathic	35	11.5	46	13.2
Status of board member				
Current member	300	98.7	360	97.8
Past member	4	1.3	8	2.2
Capacity of board member				
Physician member	241	79.3	284	77.2
Public member	46	15.1	57	15.5
Other health professional	10	3.3	16	4.3
member				
"Other" member	7	2.3	6	1.6
missing	0	0	5	1.4
Time served on board in				
years				
Mean	4.51		4.54	
Standard Deviation	4.01		3.68	
Physician members only				
Year of medical degree				
Median	1961		1966	
Currently practicing				
medicine				
Yes	229	93.5	260	89.3
No	16	6.5	31	10.7

Table 2. – Legality and Medical Acceptability of Extended Opioid Prescribing, 1991 Compared to 1997

	Level of Perceived Legality							
	Lawful and generally acceptable medical practice, with no need to investigate		Lawful and generally not acceptable medical practice which should be discouraged		Violation of medical practice laws and regulations which should be investigated		Violations of controlled substances laws which should be investigated	
Year	1991	1997	1991	1997	1991	1997	1991	1997
Cancer pain	75%	82%	14%	5%	5%	2%	5%	2%
Cancer pain with history of opioid abuse	46%	57%	22%	17%	14%	6%	12%	4%
Chronic non-cancer pain	12%	33%	47%	40%	32%	11%	27%	6%
Chronic non-cancer pain with history of opioid abuse	1%	6%	25%	36%	58%	34%	50%	20%

Note: Rows do not sum to 100% because respondents could give more than one response.