Approved: March 31, 2006
Date

MINUTES OF THE SENATE PUBLIC HEALTH AND WELFARE COMMITTEE

The meeting was called to order by Chairman James Barnett at 1:37 P.M. on March 16, 2006 in Room 231-N of the Capitol.

All members were present.

Late Arrival:

Wagle	1:39-Excused	
Haley	1:39	
	Left	1:40
	Returned	2:00
Jordan	1:39	
V. Schmidt	1:45-Excused	

Committee staff present:

Emalene Correll, Kansas Legislative Research Department
Terri Weber, Kansas Legislative Research Department
Norm Furse, Office of Revisor of Statutes
Diana Lee, Office of Revisosr of Statutes
Morgan Dreyer, Committee Secretary

Conferees appearing before the committee:

Chris Way - MICT, BA - Director EMS Labette County Medical Center
John Hultgren - MICT, I/C - Director EMS Dickinson County
Conrad Olson - MICT - President NE KS Regional EMS Council, Inc.
Chip Wheelen - Kansas Association of Osteopathic Medicine
Miranda Zorn - Individual conferee
Representative Bob Bethell
Larry Buening - Kansas Board of Healing Arts
Bob Twillman - LIFE Project Pain Management and Public Policy Task Forces
Douglas Smith - Kansas Sociey of Anesthesiologists
Rod Jones, M.D. - Pain Management L.C.
Jerry Slaughter - Kansas Medical Society
Representative Delia Garcia
Leanard Hall - Kansas Association of the Deaf, Inc.
Dr. Howard Rodenberg - Kansas Department of Health and Environment

Others attending:

See attached list.

Discussion and Action on SB 546–An act concerning the board of emergency medical services; establishing a statewide data collection system

Upon calling the meeting to order, Chairman Barnett asked for Emalene Correll to review and give new language and definitions on **HB 546**

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Chairman Barnett called upon Diana Lee to review the bill and to read a new balloon attached. A copy of the balloon is (Attachment 1) attached hereto and incorporated into the Minutes as referenced.

The Chair called the attention to written testimony whom were present at the Committee for questions.

The Chair recognized proponent conferee, Christopher Way, MICT, BA, Director, Emergency Medical Services Labette County Medical Center who stated his support for the changes that have been made to **SB 546.** A copy of his testimony is (Attachment 2) attached hereto and incorporated into the Minutes as referenced.

The Chair recognized proponent conferee, John Hultgren, MICT, I/C, Director Emergency Medical Services

MINUTES OF THE Senate Public Health and Welfare Committee at 1:37 P.M. on March 16, 2006 in Room 231-N of the Capitol.

Dickinson County stated if **SB 546** has been amended to exclude Sec. 3 then he will be supportive of passing out the proposed legislation. A copy of his testimony is (Attachment 3) attached hereto and incorporated into the Minutes as referenced.

The Chair recognized proponent conferee, Conrad Olson, MCIT, President NE Kansas Regional Emergency Medical Services Council, Inc. stated if the Task Force includes represenatation from all six EMS Regions as well as other subject experts a project will be developed that will enhance emergency medical care to our State, and he with Region V support the Board of EMS on **SB 546.** A copy of his testimony is (Attachment 4) attached hereto and incorporated into the Minutes as referenced.

With no questions or comments from the Committee, the Chair closed the discussion on **SB 546**.

The motion was made by Senator V. Schmidt that the amendments be made. It was seconded by Senator Gilstrap and the motion carried.

The motion was made by Senator V. Schmidt that the bill be moved out favorably. It was seconded by Senator Gilstrap and the motion carried.

Discussion and Action on HB 2752– An act concerning health care; relating to trauma facilities.

Chairman Barnett called upon Norm Furse to review the language and new balloons for **HB 2752.** A copy of the balloons are (Attachment 5) attached hereto and incorporated into the Minutes as referenced.

The Chair called the attention to written testimony whom were present at the Committee for questions.

The Chair recognized proponent conferee, Conrad Olson, MCIT, President NE Kansas Regional Emergency Medical Services Council, Inc. stated that as EMT's and Paramedics most know what a hospital can and cannot adequately treat. By designating hospitals in advance we will know what types of injuries a facility our local hospitals can manage and what patients we need to send to higher level care facilities. Region V support the designation of trauma facilities in Kansas. A copy of his testimony is (Attachment 6) attached hereto and incorporated into the Minutes as referenced.

With no questions or comments from the Committee, the Chair closed the discussion on **HB 2752**.

The motion was made by Senator V. Schmidt to move both amendments on both pages, the stricken language and added balloons. It was seconded by Senator Jordan and the motion carried.

The motion was made by Senator V. Schmidt that the bill be moved out favorably. It was seconded by Senator Wagle and the motion carried.

Hearing on HB 2649–An act concerning health care; relating to pain patient's bill of rights

Chairman Barnett opened the hearing on **HB 2649**, and asked Emalene Correll to review again the language of **HB 2649** for the Committee.

The Chair called upon first proponent conferee, Chip Wheelen, Kansas Association of Osteopathic medicine stated that the revised section two would make it clear that the "pain patient's bill of rights" is a statement of public policy; not a new cause of action that could result in civil lawsuits against physicians. That the revised version of section three amends the Healing Arts Act to assure that those physicians who prescribe pain medication, including narcotics, in accordance with the applicable standard of care will not be disciplined by the Board of Healing Arts for that reason. And that the new language in section four simply adds balance and clarity to the bill by making it clear that it is not the Legislature's intent to impair the Board's role as a regulatory agency, nor to interfere with the investigative authority fo law enforcement agencies therefore recommending the bill for passage. A copy of his testimony is (Attachment 7) attached hereto and incorporated into the Minutes as referenced.

MINUTES OF THE Senate Public Health and Welfare Committee at 1:37 P.M. on March 16, 2006 in Room 231-N of the Capitol.

Chairman Barnett called upon the next proponent conferee, Miranda Zorn, an individual conferee who stated her experience as a patient getting an "staph-like infection" from a shot given to her at the hospital. And a bad experience in surgery not receiving enough anesthesia. A copy of her testimony is (Attachment 8) attached hereto and incorporated into the Minutes as referenced.

Chairman Barnett called upon the third proponent conferee, House Representative Bob Bethell who stated his support for **HB 2649** that is a product of several years of study and negotiations resulting in a bill that will provide appropriate pain management for persons suffering from the affects of medical treatment or natural progression of disease. A copy of his testimony is (Attachment 9) attached hereto and incorporated into the Minutes as referenced.

The Chair called upon the next proponent conferee, Larry Buening, Kansas Board of Healing Arts stated that the Board has been working with Dr. Twillman to offer four new amendments to the Committee and that the Board is supportive of the concept of a Pain Patients' Bill of Rights, but asks that the Committee favorably consider the amendments requested. A copy of his testimony is (Attachment 10) attached hereto and incorporated into the Minutes as referenced.

Chairman Barnett called upon the next proponent conferee, Bob Twillman, Ph.D., LIFE Project Pain Management and Public Policy Task Forces, stated that despite our superb public policy and supportive regulatory boards, available statistics indicates that the quality of pain management in Kansas is below average. And states the importance of certain sections that make the bill important in promoting the relief of pain for all Kansans by adopting **HB 2649**. A copy of his testimony is (Attachment 11) attached hereto and incorporated into the Minutes as referenced.

The Chair called upon the last proponent conferee, Douglas Smith, Kansas Society of Anesthesiologists who states that the bill provides patients suffering from pain with certain expectations in regard to the care and treatment they receive. They encourage that the legislation be passed out favorably. A copy of his testimony is (Attachment 12) attached hereto and incorporated into the Minutes as referenced.

Chairman Barnett called upon his first opponent conferee, Rod Jones, M.D., Pain Management L.C. states that **HB 2649** was initially drafted to improve access to adequate pain relief for terminal cancer and dying patients, its application to non-malignant pain patients, as well as, many cancer patients is misdirected. He also provides an article on "Opioid Guidelines in the Management of Chronic Non-cancer Pain." A copy of his testimony is (Attachment 13) attached hereto and incorporated into the Minutes as referenced.

The Chair called upon his first neutral conferee, Jerry Slaughter, Kansas Medical Society states that they are in conceptual support of the intent of the bill, but they are concerned about how, in the real world, its provisions will play out. They would be more than willing to meet with the stakeholders in this issue and continue to work on language that advances the goals of th bill without creating problems that could actually make the assessment and treatment of pain more problematic. The Kansas Medical Society urges the Committee to not take action on this measure until the groups have had a chance to meet and consider appropriate alternatives. A copy of his testimony is (Attachment 14) attached hereto and incorporated into the Minutes as referenced.

Chairman Barnett announced that written testimony was offered from Deanne Bacco, Kansas Advocates for Better Care, Laura Green, Executive Director for Drug Policy Forum of Kansas, and Phyllis Zorn, Mother of Miranda Zorn, individual conferee. A copy of this testimony is (Attachment 15) attached hereto and incorporated into the Minutes as referenced.

With no more conferees' to give testimony and no questions or comments from the Committee, Chairman Barnett then closed the hearing on **HB 2649**.

Hearing on HB 2825–An act providing for establishment of a voluntary data bank of available interpreters for certain purposes and development of qualifications for interpreters

Chairman Barnett opened the hearing on **HB 2825**, and asked Emalene Correll to review the language and

explain **HB 2825** for the Committee.

Chairman Barnett called upon the first proponent conferee, House Representative Delia Garcia who states that **HB 2825** leads to greater safety and protection measures for all Kansans. It provides for this voluntary, comprehensive data bank of interpreters as a resource for Kansans in the health care field, not just the court system. This bill minimizes medical errors, while increasing the quality of care for Kansans, because these interpreters will know the medical terminology. Therefore, this bill will encourage people to seek out early services by having an interpreter in a safe environment. A copy of this testimony is (Attachment 16) attached hereto and incorporated into the Minutes as referenced.

The Chair called upon the next proponent conferee, Leonard Hall, President of Kansas Association of the Deaf, Inc., who states that there is a major need to provide for standards and data bank of Foreign Language Interpreters, because there are no standards and data bank fo them in Kansas. Amendments to the bill and language are provided. A copy of this testimony is (Attachment 17) attached hereto and incorporated into the Minutes as referenced.

Chairman Barnett called upon the last proponent conferee, Dr. Howard Rodenberg, Director, Division of Health, Kansas Department of Health and Environment states that KDHE is in support of the bill as revised. The bill provides for a mechanism to establish a voluntary data bank and directory of available interpreters to assist Kansans in obtaining meaningful access to needed health care. A copy of this testimony is (Attachment 18) attached hereto and incorporated into the Minutes as referenced.

Chairman Barnett announced that written proponent testimony was offered from Karrie Bacon, Kansas Commission on Disability Concerns, Linda De Coursey, American Heart Association, Gabriela Flores, Executive Committee Member, Foreign Language Interpreter Consortium of Kansas Association of Interpreters, Nancy Jorn, MN, ARNP, Director of Maternal Child Health Field Services Lawrence/Douglas County Health Department, Zach Campbell, Jewish Vocational Service Trilingual Employment Specialist, Maria Cecilia Ysaac-Belmares, A+ Communications, Owner; Executive Committee Member, Foreign Language Interpreter Consortium of Kansas Association Of Interpreters, Marcela Renna, World Languages, freelance Spanish Interpreter. A copy of this testimony is (Attachment 19) attached hereto and incorporated into the Minutes as referenced.

Chairman Barnett announced that written neutral testimony was offered from Capt. Edwin Galan, USPHS, Region VII, DHHS, Office of Minority Health, Gary Daniels, Secretary, Kansas Department of Social and Rehabilitation Services. A copy of this testimony is (Attachment 20) attached hereto and incorporated into the Minutes as referenced.

With no more conferees' to give testimony and no questions or comments from the Committee, Chairman Barnett then closed the hearing on **HB 2825.**

Hearing on HCR 5011–A concurrent resolution expressing the Legislature's recognition and appreciation for family caregivers throughout the state

Chairman Barnett opened the hearing on **HCR 5011**.

Chairman Barnett announced that written proponent testimony was offered from Karrie Bacon, Kansas Commission of Disability Concerns, Alyce Brown, AARP Kansas. A copy of this testimony is (Attachment 21) attached hereto and incorporated into the Minutes as referenced.

With no more conferees' to give testimony and no questions or comments from the Committee, Chairman Barnett then closed the hearing on **HCR 5011.**

The motion was made by Senator Brungardt to move the bill out on the consent calendar. It was seconded by Senator V. Schmidt and the motion carried.

Adjournment

MINUTES OF THE Senate Public Health and Welfare Committee at 1:37 P.M. on March 16, 2006 in Room 231-N of the Capitol.

As there was no further business or time, the meeting was adjourned at 2:30 p.m.

PH&W March 16, 2006

Sign In

Robert Twillman LIFE Project Robert Twillman
Chad Austin KS Hosp Assoc
Melissa Hungerford "
Miranda Eaton citizen/proponent
Phyllis Zora citizen/proponent
Kary Buening - Bd of Healing Arts
Leonard Hall President of KS Assoc of Deaf
Conrad Olson President Region V EMS Council
Robert Walker KBEMS
JOE MORELAND BOARD OF EMS
Mary E Mulyan Board of EMS
Rosanne Rutkowski KDHE
Dick Morrissey KDHE
Carolyn Mendenhall KS St Nurses Assn
Brent Wilcox SRS
Lenora Rice KS Assn of Nurse Anesthetists
Kim Lynch KFMC
J. Vossegard self
E Kuckelman AHIP
Doug Smith Rebecca Connelly
Ks Society of Anesthesiologist

Senate Public
Health & Welfare

Wed., March 15, 2005

Session of 2005

SENATE BILL No. 546

By Committee on Ways and Means

2-10

AN ACT concerning the board of emergency medical services; establishing a statewide data collection system.

Be it enacted by the Legislature of the State of Kansas:

Section 1. (a) The board of emergency medical services shall develop and maintain a statewide data collection system to collect and analyze emergency medical services information, including, but not limited to, dispatch, demographics, patient data, assessment, treatment, disposition, financial and any other pertinent information that will assist the board in improving the quality of emergency medical services.

(b) Each operator of an ambulance service shall collect and report to the board emergency medical services information pursuant to rules and regulations adopted by the board. The board shall adopt rules and regulations which use the most efficient, least intrusive means for collecting emergency medical services information consistent with ensuring the quality, timeliness, completeness and confidentiality of the system.

Sec. 2. (a) Any emergency medical services information provided to the board shall be confidential and shall not be disclosed or made public, upon subpoena or otherwise, except such information may be disclosed if:

(1) No person can be identified in the information to be disclosed and the disclosure is for statistical purposes;

(2) all persons who are identifiable in the information to be disclosed consent in writing to its disclosure; or

(3) the disclosure is necessary, and only to the extent necessary, to protect the public health and does not identify specific operators or ambulance services.

(b) Except as provided in subsection (c), reports generated by the board utilizing emergency medical services information shall be available in accordance with K.S.A. 45-215 et seq., and amendments thereto.

(c) Notwithstanding subsection (b), individually identifiable health information shall be confidential and shall not be disclosed except that the board may disclose such information to individuals, organizations or governmental agencies engaged in research that benefits the public's health, safety or welfare if the board is satisfied that such information will remain

Within the limits of appropriations therefore, the

persons,

, as defined in K.S.A. 65-6112, and amendments thereto,

Senate Public Health & Welfare Committee
Date: March 16, 2006
Attachment #1

confidential and adequately protected from disclosure. For purposes of this section, "individually identifiable health information" shall have the same meaning as in 45 C.F.R. § 160.103.

~~Sec. 3. (a) The board may, in accordance with the Kansas administrative procedure act, restrict or prohibit eligibility for grants or may impose fines not to exceed $1000 per occurrence, or both, for failure to submit emergency medical services information within time frames prescribed by the board in rules and regulations.~~

~~(b) All fines assessed and collected under this section shall be remitted to the state treasurer in accordance with the provisions of K.S.A. 75-4215, and amendments thereto. Upon receipt of each such remittance, the state treasurer shall deposit the entire amount in the state treasury to the credit of the state general fund.~~

STRIKE SECTION 3 & REUMBER SECTIONS ACCORDINGLY

Sec. 4. Any operator who reports emergency medical services information, in good faith, and in accordance with the requirements of this act and the rules and regulations prescribed by the board, shall have immunity from any liability, civil or criminal, which might otherwise be incurred or imposed in an action resulting from such information. Nothing in this section shall be construed to apply to the unauthorized disclosure of confidential information when such disclosure is due to gross negligence or willful misconduct.

3

Sec. 5. Sections 1 through ~~4~~, and amendments thereto, shall be part of and supplemental to the provisions of article 61 of chapter 65 of the Kansas Statutes Annotated and acts amendatory of the provisions thereof or supplemental thereto.

Sec. 6. This act shall take effect and be in force from and after its publication in the statute book.

From: "Chris Way" <cway@lcmc.com>
To: <barnett@senate.state.ks.us>
Date: Tue, Mar 14, 2006 2:29 PM
Subject: SB 546

Senator Barnett,

I would like to take a minute to express my support for the changes that have been made to Senate Bill 546. As I stated in my earlier testimony The Kansas EMS association certainly supports the idea of data collection but did not support the idea of punitive action to get it done. With the changes that have been made we stand in full support of the bill now. If I can be of any further help please let me know. I appreciate your support of the EMS community on this issue.

Christopher Way MICT, BA
Director, Emergency Medical Services
Labette County Medical Center
1902 South Hwy 59
Parsons, Kansas 67357
Phone 620-421-2401
Fax 620-820-5488
Pager 620-454-8006

Senate Public Health & Welfare Committee
Date: March 16, 2006
Attachment #2

DICKINSON COUNTY EMERGENCY MEDICAL SERVICES

511 NE 10th, Abilene, Kansas 67410

March 9, 2006

Kansas Board of EMS
Attn: Robert Waller
911 SW Jackson, Rm 1031
Topeka, Kansas 66612-1228

Robert,

I am writing this letter on behalf of Region IV EMS and as Director of Dickinson County EMS.

The testimony that I presented to the senate committee last week in regards to SB546 stated that we as a region were highly supportive of statewide data collection. Our concern was in Sec. 3 that dealt with penalties for slow or absent submission of data to the state. We felt this was unfair and would be reacted to very negatively by services that may need some to comply.

As we understand in communication with you, SB546 has been amended to exclude Sec. 3. We feel this is a very positive step for the bill. With this change, and your willingness to work with the six EMS Regions on a Data Collection Task Force that will help develop and outline the rules and regulations concerning the data collection process, we are supportive of the current amended version of SB546.

Respectfully,

John Hultgren

John Hultgren, MICT I/C
EMS Director

Senate Public Health & Welfare Committee
Date: March 16, 2006
Attachment #3

Region V EMS

NE Kansas EMS Council, Inc.

A Not-for-profit corporation

March 15, 2006

To: Senate Public Health and Welfare Committee

From: Conrad L. Olson, MICT
President NE Kansas Regional EMS Council, Inc.

Re: Testimony in Support of SB 546

Good afternoon, I am Con Olson, and I am currently a Paramedic serving in rural NE Kansas, in addition I am also the President of the NE Kansas Region V EMS Council.

Mr. Chairman and Committee Members I appreciate the opportunity to provide testimony here today in support of SB 546.

As we have heard in previously EMS professionals from across the State are in support of data collection. Our Region like others had similar concerns about the implementation of the data collection project.

My Region also supports the Task Force agreed upon by Mr. Waller. We believe this work group should survey the technological needs and potential expenses of services as well as develop regulations that outline the collection process and the implementation time frame.

In closing I feel comfortable in saying as long as the Task Force includes representation from all six EMS Regions as well as other subject experts a project will be developed that will enhance emergency medical care to our State. We at Region V support the Board of EMS on SB 546.

Again thank you for your time and I would be willing to stand for questions.

Con Olson Region V President
1250 Walnut St.
Oskaloosa, KS 66066

Region V EMS Council
804 Cowell St. PO Box C
Paola, KS 66071

Senate Public Health & Welfare Committee
Date: March 16, 2006
Attachment # 4

Session of 2005

HOUSE BILL No. 2752

By Committee on Health and Human Services

1-27

AN ACT concerning health care; relating to trauma facilities; amending K.S.A. 2005 Supp. 75-5665 and 75-5666 and repealing the existing sections.

Be it enacted by the Legislature of the State of Kansas:

Section 1. K.S.A. 2005 Supp. 75-5665 is hereby amended to read as follows: 75-5665. The secretary of health and environment, after consultation with and consideration of recommendations from the advisory committee, shall:

(a) Develop rules and regulations necessary to carry out the provisions of this act, *including* ~~[providing for fees to support]~~ *the designation of trauma facilities pursuant to subsection (f) of this section*;

fixing, charging and collecting fees from trauma facilities to recover all or part of the expenses incurred in

(b) develop a statewide trauma system plan including the establishment of regional trauma councils, using the 1998 Kansas EMS-Trauma Systems Plan study as a guide and not more restrictive than state law. The secretary shall ensure that each council consist of at least six members. Members of the councils shall consist of persons chosen for their expertise in and commitment to emergency medical and trauma services. Such members shall be chosen from the region and include prehospital personnel, physicians, nurses and hospital personnel involved with the emergency medical and trauma services and a representative of a county health department. The plan should:

(1) Maximize local and regional control over decisions relating to trauma care;

(2) minimize bureaucracy;

(3) adequately protect the confidentiality of proprietary and personal health information;

(4) promote cost effectiveness;

(5) encourage participation by groups affected by the system;

(6) emphasize medical direction and involvement at all levels of the system;

(7) rely on accurate data as the basis for system planning and development; and

(8) facilitate education of health care providers in trauma care;

(c) plan, develop and administer a trauma registry to collect and an-

Senate Public Health & Welfare Committee
Date: March 16, 2006
Attachment # 5

alyze data on incidence, severity and causes of trauma and other pertinent formation which may be used to support the secretary's decision-making and identify needs for improved trauma care;

(d) provide all technical assistance to the regional councils as necessary to implement the provisions of this act;

(e) collect data elements for the trauma registry that are consistent with the recommendations of the American college of surgeons committee on trauma and centers for disease control;

(f) designate trauma facilities by level of trauma care capabilities after considering the American college of surgeons committee on trauma standards and other states' standards;

except that trauma level designations shall not be based on criteria that place practice limitations on registered nurse anesthetists which are not required by state law

~~(f)~~ *(g)* develop a phased-in implementation schedule for each component of the trauma system, including the trauma registry, which considers the additional burden placed on the emergency medical and trauma providers;

~~(g)~~ *(h)* develop standard reports to be utilized by the regional trauma councils and those who report data to the registry in performing their functions;

~~(h)~~ *(i)* assess the fiscal impact on all components of the trauma system, and thereafter recommend other funding sources for the trauma system and trauma registry;

~~(i)~~ *(j)* prepare and submit an annual budget in accordance with the provisions of this act. Such budget shall include costs for the provision of technical assistance to the regional trauma councils and the cost of developing and maintaining the trauma registry and analyzing and reporting on the data collected; and

~~(j)~~ *(k)* enter into contracts as deemed necessary to carry out the duties and functions of the secretary under this act.

Sec. 2. K.S.A. 2005 Supp. 75-5666 is hereby amended to read as follows: 75-5666. (a) The secretary of health and environment shall develop and maintain a statewide trauma registry ~~and consult with the health care data governing board in developing the registry~~. All ~~designated trauma centers,~~ prehospital trauma providers, designated trauma facilities and ~~acute~~ medical care facilities that provide any service or care to or for persons with trauma injury in this state shall collect and report to the trauma registry data and information deemed appropriate by the secretary~~, after consultation with the health care data governing board,~~ to monitor patient outcome.

(b) The secretary is hereby authorized to collect data pertaining to all trauma care occurring in Kansas. The secretary shall adopt rules and regulations which use the most efficient, least intrusive means for collecting the trauma care data consistent with ensuring the quality, timeliness, completeness and confidentiality of the trauma registry.

5-2

(c) Any health care provider, whether a person or institution, who ports trauma information to the registry in good faith and without mal-e, in accordance with the requirements of this section, shall have immunity from any liability, civil or criminal, which might otherwise be incurred or imposed in an action resulting from such report. Notwithstanding K.S.A. 60-427 and amendments thereto, there shall be no privilege preventing the furnishing of such information or reports as required by this act by any health care provider. Nothing in this section shall be construed to apply to the unauthorized disclosure of confidential or privileged information when such disclosure is due to gross negligence or willful misconduct.

(d) The information obtained by the trauma registry, including discussions and activities using the information generated from the trauma registry, shall be confidential and shall not be disclosed or made public, upon subpoena or otherwise, except such information may be disclosed if:

(1) No person can be identified in the information to be disclosed and the disclosure is for statistical purposes;

(2) all persons who are identifiable in the information to be disclosed consent in writing to its disclosure;

(3) the disclosure is necessary, and only to the extent necessary, to protect the public health~~, and does not identify providers or facilities, or~~ *and to support quality improvement as defined in K.S.A. 65-4914 and 65-4915, and amendments thereto; or*

(4) the information to be disclosed is required in a court proceeding involving child abuse and the information is disclosed *in camera*.

Sec. 3. K.S.A. 2005 Supp. 75-5665 and 75-5666 are hereby repealed.

Sec. 4. This act shall take effect and be in force from and after its publication in the statute book.

5-3

Region V EMS

NE Kansas EMS Council, Inc.

A Not-for-profit corporation

March 13, 2006

To: Senate Public Health and Welfare Committee

From: Conrad L. Olson, MICT
President NE Kansas Regional EMS Council, Inc.

Re: **Written Testimony for HB 2752**

Good afternoon, I am Con Olson, and I am currently a Paramedic serving in a rural setting here in NE Kansas and in addition, I am also the President of the NE Kansas Regional EMS Council. From my experiences working as a rural Paramedic I have seen first hand how our patients, your constituents, have benefited from our developing trauma system.

I am submitting this written testimony in support of HB 2752. It is of utmost importance that all of our hospitals in the State have a trauma designation, based upon proven National and Professional Standards. Whether it is a "trauma receiving facility" or a "Level I trauma center" all facilities in Kansas no matter if it is a small rural hospital or a large regional center should have a designation.

We as EMT's and Paramedics most know what a hospital can and cannot adequately treat. By designating hospitals in advance we will know what types of injuries a facility our local hospital(s) can manage and what patient(s) we need to send to higher level of care facilities.

If we transport a critically injured patient to a facility will not have the capabilities to treat their injuries does the patient no good. The time lost at a facility that will have to transfer a patient could cost this person their life. If we know a facilities' capability in advance we can judge whether or not a patient should be treated local first. However, sometimes we will have to drive or fly patients farther bypassing our local hospital to a facility that can handle the injury may be of benefit to the patient.

The same is true in reverse for less critical patients. If a local hospital has committed to having a designation, at a level of care which they can support, is a positive for everyone. We as EMS providers and our citizens can rest comfortably in knowing we can care for our own citizen(s) in the local community when they have serious less critical injuries. This allows for families to stay close to home, recover with the aide of local medical staff, decreases the overload of less critical patients on major trauma centers, keeps local healthcare dollars at home and decreases medical costs.

In closing we at Region V support the designation of trauma facilities in Kansas. As we have pointed out this gives our citizens an even higher quality of care locally and regionally, as well as many impacts far beyond patient care.

Thank you.

Con Olson Region V President
1250 Walnut St.
Oskaloosa, KS 66066

Region V EMS Council
804 Cowell St. PO Box C
Paola, KS 66071

Senate Public Health & Welfare committee
Date: March 16, 2006
Attachment # 6

Kansas Association of Osteopathic Medicine
1260 SW Topeka Boulevard
Topeka, Kansas 66612
Phone (785) 234 5563
Fax (785) 234 5564

Testimony on House Bill 2649
To The
Senate Public Health and Welfare Committee
By Charles L. (Chip) Wheelen
March 16, 2006

Thank you for the opportunity to express our support for the amended version of HB 2649. We did have concerns about the original bill, but those reservations have been addressed by the House Committee amendments.

The revised section two would make it clear that the "pain patient's bill of rights" is a statement of public policy; not a new cause of action that could result in civil lawsuits against physicians. We believe this is an important distinction.

The revised version of section three amends the Healing Arts Act to assure that those physicians who prescribe pain medication, including narcotics, in accordance with the applicable standard of care, will not be disciplined by the Board of Healing Arts for that reason. Perhaps equally important, the new language would require the Board of Healing Arts to support a physician who has adhered to the Board's guidelines for prescribing controlled substances, if that physician is investigated by another government agency.

The new language in section four simply adds balance and clarity to the bill by making it clear that it is not the Legislature's intent to impair the Board's role as a regulatory agency, nor to interfere with the investigative authority of law enforcement agencies.

During House Committee hearings questions were raised regarding the extent to which this bill would apply to non-physician prescribers of narcotics. We offered the opinion that because the language supplements and amends the Healing Arts Act, it would not apply to dentists nor to podiatrists. We also expressed the opinion that it would offer protections to those allied health professionals who prescribe narcotics in accordance with established protocols. This is based on the premise that when a physician assistant or nurse practitioner prescribes medication, they are practicing medicine and surgery pursuant to delegation by the physician who established the protocols for the allied health care professional.

Thank you for considering our testimony. We respectfully request that you recommend HB2649 for passage by the Senate.

Senate Public Health & Welfare Committee
Date: March 16, 2006
Attachment # 7

Testimony in favor of "The Pain Patients Bill of Rights"

Miranda Zorn

On December 26, 2004, I went to the emergency room for what I thought was strep throat. Cultures were run, along with a sinus X-Ray, and it was determined that I had a virus. I was given a shot to make me feel better.

On January 2, I was seen in the ER again because the injection site had become severely painful, swollen and red in color. I was put on antibiotics and warned about what might be to come. A week later, the abscess started to drain, and a third visit to the ER was needed to run a culture. I was told to schedule an appointment with my physician on Monday.

After scheduling my appointment, the doctor's office called and said that I had been transferred from my regular physician to the infectious disease specialist. Upon arriving, we were taken right in. The nurse looked me over. She left and the doctor came in a couple of minutes later. He was unsure of why my appointment had been switched to him; we told him the lab results were to have come in that morning. He went to fetch them and was back within two minutes. He said the results showed a "staph-like infection," which was immediately followed by: "I can't prove it was the needle."

He then looked me over and told me that it had to be drained right away. There was still far too much infection under there for me to just keep taking the antibiotics. I grimaced and told him I wasn't looking forward to that. He and the nurse both assured me that the worst part of the surgery was going to be the shot to numb everything. I

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smiled and told him that I was glad.

When they prepped me for surgery, I remember thinking how glad I was that my mom had come with me; I wasn't sure if I'd have been able to drive myself home. Then, as it turned out, driving myself home was to be the least of my worries.

The shot hurt a bit, as expected. And with the incision, there was a bit of pressure, but no pain. So far, so good, I thought to myself. Then came the draining.

At first, it just hurt from the pressure of the doctor draining the abscess, and that was okay. Then, slowly, the pain became sharp and no longer just from the pressure. I held my breath, trying to keep from crying, which didn't work. I start crying anyway. The pain became unimaginable. I thought the shot was going to be the worst part; that was nothing compared to this. It was worse than I can even put into words. As I was lying on the table sobbing, the doctor behind me asked "Oh, does it hurt?" Since I was sobbing too much to answer, my mother responded with, "Do you think she would be crying if it didn't hurt?" The doctor said nothing back, just kept going. My mom asked if there was something else he could do, another shot maybe. He said there was nothing; since the incision had already been made, the field was unsterile and another shot would just start the whole cycle over again. So Mom just held my hand tighter and told me it was going to be over soon. Just then, when I thought the pain couldn't get any worse, I felt like I was being cut with a dull knife with no anesthetic at all. It felt like something was being ripped out of me. I screamed out, and the doctor said, "I'm sorry, I'm sorry, I'm sorry." And while he sounded sincere, it didn't make any difference – it didn't make the pain go away, nor did it lessen it any. And just when I thought for sure that that had

to have been the worst of it, I felt the same ripping feeling again, only this time it was worse. It was pure torture. I don't know how else to describe it. This time, as I screamed out, the doctor again apologized and said that was almost done. True to his word, he was. A few minutes later, he told me that he was done draining it and all he had left was packing and dressing. I breathed a sigh of relief between sobs, thinking to myself that packing can't be too bad.

Since the pain was lessened, I tried to quit crying. (Really, all I did was go from screaming down to mildly sobbing.) As I was trying to recover, the nurse was getting the dressing and packing ready. The doctor explained to my mom that what he had done at the end was repeatedly reach his finger in to pull out some of the infection, and then showed her why it was so important that he do it.

Once they were all ready to pack and dress, he warned me they were going to start again. I nodded my head as I sobbed to let him know I understood. At first, the packing wasn't so bad. Then, the more he packed, the more it hurt, and it quickly escalated to hurting so badly that I was again screaming. The only consolation was that at least the packing was much quicker that the surgery itself.

After I was packed, the doctor explained that the packing was not to be changed by us; he would call down to Special Nursing Services and arrange for them to change the packing and dressing everyday starting tomorrow, but that the dressing was going to need changed 3 or 4 times before my appointment. He asked the nurse to show Mom how to change the dressing so he could call down to Special Nursing Services and to the pharmacy. The nurse showed my mom how to change the dressing as I slowly started to

cry less, and then she stayed with me while Mom went to call work to tell them she would not be back that day. (She also signed papers to have the records released.) The nurse came over and brought me facial tissue and asked how I was doing. I told her better; she said, "Better, but not really?" and I laughed a little bit. She told me I could stay in the room until I was ready, to take my time getting dressed.

By the time my mom came back, I had quit crying almost altogether. The doctor came back in and said that he had called the pharmacy and prescribed more Keflex and another antibiotic, along with Loritab. He also said that Special Nursing Services would be calling us that night to set up an appointment for the next day. He, also, told me to take my time getting around if I needed to.

When the doctor and nurse left, I slowly started sitting up. Every move I made hurt, and I started crying a little again. It took what felt like hours to sit up and get off of the table, but probably only took five minutes. The doctor came back in to check on me as I was getting dressed. He said the pharmacy would have my pills ready when we got there. He said the painkiller should be plenty strong enough, but if it wasn't, I could also take aspirin. He told me that for having the abscess repacked, one pill should also be enough.

The pills were fine for getting me through the rest of the day and the morning on Tuesday. And, like I was instructed, I just made sure to take my pills on schedule.

I arrived at my appointment at Special Nursing Services at 1:30. I had taken my pain pill at 12:30. When the nurse took the packing out, it hurt so bad I about flew off of the cot. At least it was quick and I didn't cry. She said that based on the amount of

packing she pulled out, that doctor "must have used an entire bottle of packing." She told me to relax; she'd get me a blanket and a pop and call up to my doctor to get something else prescribed for while she was changing the packing. She brought my pop and blanket and then left for a while.

She came back ten minutes later and said that the doctor treating my infection wasn't in, but she spoke to his partner, my regular physician. He had initially said that I was to receive no more pain medication, that those pills should be plenty. She told him that she would not repack it without more pain control. He then, reluctantly, told her that I could have 12.5 mg of Demerol, and that if after ten minutes I still needed more, to give me the other 12.5 mg. She said that should could either give me a shot, at which point I made a sour face, or she could put in an IV. I explained that I was a little leery of another shot and I'd rather have an IV. She said that was her pick, too, especially since I'd never received Demerol prior to this. So, she explained to me what was going to do since I'd never had an IV before. She found a good vein, gave me a shot to numb the area and then put in the IV. She called down the wound care specialist to help her decide what to pack and dress with. I was initially given just 12.5 mg of Demerol as instructed. When the wound was being measured it still hurt terribly, so the nurse got ready to give me the rest of the Demerol. (The wound measured at 3.6 cm deep, 2 cm long and 1 cm wide.) The wound care specialist worked very quickly, and by the time the other 12.5 mg of Demerol had gotten into my blood, she was already done.

After we received the records, we learned what the doctor had done to numb the area before he drained: his records show he numbed only the surface area with lidocaine,

not the deep tissue. This explains why draining out the abscess hurt so badly. Also, along with repeatedly reaching in with his finger, a second incision was also made inside the abscess, all without the aid of anesthesia.

We have since learned that there were several other things that could have been done to give me more pain control when we asked for it. For example, I could have been given a shot in my arm; I could have been given a fast acting pill; I could have had an IV put in my hand. One doctor said that he, upon seeing the extent of the abscess, would have stopped surgery and called a surgeon and an anesthesiologist.

Here's the way I see it: I understand that doctors are afraid to over prescribe. However, I strongly feel that if pain medication is used simply for pain control, then health care professionals should have no fear of repercussion for treating a patient's pain. A patient's comfort should take a backseat only to getting that patient well. I feel there is no reason for someone to have had to go through what I went through. It was torture, plain and simple, and I would wish it on no other living being.

I feel that if this bill didn't need to be passed, this would not have happened to me. I came through it with just a scar and some bad memories, but I survived. This is about making sure it doesn't happen to anyone else in the future.

Thank you for your time and prompt attention to this matter.

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STATE OF KANSAS

TOPEKA

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March 16, 2006

Testimony on HB 2649

Good afternoon Chairman Barnett and members of Public Health and Welfare Committee, my name is Bob Bethell and I represent the 113th District in the Kansas House of Representatives.

It is my pleasure to be here today and request your support for HB 2649. HB 2649 is a product of several years of study and negotiation resulting in a bill that will provide appropriate pain management for persons suffering from the affects of medical treatment or natural progression of disease.

HB 2649 has been scrutinized by, I believe, all interested parties. Various physicians groups, the public and the Life Project played a vital role in the drafting and the final product that you have before you today. While it gives the right to persons to be treated for the pain that they experience it also protects those who provide that relief from frivolous pursuit. HB 2649 also provides a process that would require a person who may be demanding medication for reasons other than pain management to be seen by an expert in the field of pain management.

I strongly urge you to support the passage of HB 2649 without any amendments.

Thank you Mr. Chairman and members of the Health Care Strategies Committee, I will stand for questions.

Senate Public Health & Welfare Committee

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Attachment # 9

KANSAS BOARD OF HEALING ARTS

LAWRENCE T. BUENING, JR.
EXECUTIVE DIRECTOR

KATHLEEN SEBELIUS
GOVERNOR

MEMO

TO: Senate Committee on Public Health and Welfare

FROM: Lawrence T. Buening, Jr.
Executive Director

DATE: March 16, 2006

RE: Testimony on H.B. No. 2649, as amended by House Committee

Thank you for the opportunity to appear before you and provide information on H.B. No. 2649, as it was amended by the House Health and Human Services Committee. The Board as a whole reviewed the original version of the bill at its meeting February 10, 2006. At that meeting, Robert Twillman, Ph.D., Jerry Slaughter, Kansas Medical Society, and Charles L. Wheelen, Kansas Association of Osteopathic Medicine, were all present and provided information to the Board. The Board adopted a position to support the concept of a Pain Patient's Bill of Rights, but directed staff to study the bill and any amendments to be sure there would be no unintended consequences of adoption.

The Board did not provide testimony to the House Committee. However, the Board has been working very closely with Dr. Twillman even before the bill's introduction, particularly with regard to the amendments made to K.S.A. 65-2837(b)(23) which appear on page 6, lines 10 through 15.

For many years, the Board has been concerned that citizens of Kansas receive appropriate pain management. In October 1998, the Board adopted Guidelines for the Use of Controlled Substances for the Treatment of Pain. Subsequently, meetings were held with representatives of the Boards of Nursing and Pharmacy and the four professional associations involved. As a result, in 2002, Kansas became the first state to adopt a Joint Policy Statement of the Boards of Healing Arts, Nursing and Pharmacy on the Use of Controlled Substances for the Treatment of Pain. In that document, inappropriate treatment of pain was defined to include "nontreatment, undertreatment, overtreatment, and ineffective treatment". Both of these documents can be accessed from the Board's website at www.ksbha.org by clicking on "Public Information" and then clicking on "Policy Statements". Both Donna Bales and Dr. Twillman provided great assistance in the development of the Joint Policy Statement.

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In September 2005, I attended a forum sponsored by the Kansas LIFE Project on pain management at which Dr. Twillman was a presenter. Dr. Twillman noted that the Pain & Policy Studies Group at the University of Wisconsin had continually given the state of Kansas high marks for its pain management policy. However, one negative factor that has continually been noted by that organization is the ambiguity of K.S.A. 65-2837(b)(23). Therefore, we have worked through Dr. Twillman to arrive at language that might be more appropriate. The language on page 6 at lines 10-15 is a product of a collaborative effort to meet the concerns that have been raised by the Pain & Policy Studies Group.

After studying the amendments made to H.B. No. 2649 by the House Committee, we have worked with Dr. Twillman to address some concerns we had about some of these changes. Therefore, the Board would offer the following amendments:

(1) Delete subsection (c) of new section 2 in its entirety and re-letter the remaining subsections accordingly.
(2) Totally amend subsection (d) of Section 3 to read as follows:

"(d) The board shall adopt guidelines and may adopt rules and regulations for the use of controlled substances for the treatment of pain. The guidelines and any rules and regulations shall be consistent with the provisions of New Sec. 2 of this act. Upon request of another regulatory or enforcement agency or a licensee, the Board may conduct an investigation and render a written advisory opinion indicating whether the licensee has prescribed, dispensed or administered controlled substances, including opioid analgesics, in accordance with guidelines or any rules and regulations adopted by the board."

(3) Delete new section 4 in its entirety and renumber the remaining sections accordingly.

(4) Add the following sentence on Page 6, line 15: "The board shall consider prescribing, ordering, administering or dispensing of controlled substances for pain to be for a legitimate medical purpose if based on sound clinical grounds." (Note: this is currently the same language as the second sentence of current Sec. 3, subsection (d).

I would be happy to go into the reasons for these suggested amendments. However, these changes have been agreed to by Dr. Twillman and the LIFE Project and I do not want to take more of your time than absolutely necessary.

In conclusion, the Board is supportive of the concept of a Pain Patients' Bill of Rights, but asks that you favorably consider the amendments above requested. Thank you for the opportunity to appear before you and I would be happy to respond to any questions at the appropriate time.

Testimony on HB2649
Senate Public Health and Welfare Committee
Robert Twillman, Ph.D.
LIFE Project Pain Management and Public Policy Task Forces
March 16, 2006

It is my pleasure to speak to you today in support of HB2649, the Pain Patient's Bill of Rights, submitted by Representative Bethell, and passed by the House on a vote of 125-0. It is my belief that this bill represents a significant addition to existing public policy related to pain management in Kansas. Experts who evaluate public policy related to pain management have consistently given Kansas high marks for its policies, and I believe that the additions proposed in this bill will produce a rating that is second to no other state's.

As I testified when I last spoke with the Health Care Strategies Committee, poor pain management is a significant public health concern. For a variety of reasons, patients with pain experience great difficulty in receiving adequate treatment from their physicians and other healthcare providers, resulting in serious decrement to their quality of life. Uncontrolled pain causes disability, anxiety, anger, depression and despair, and, in the most extreme cases, suicide. The National Institutes of Health estimate that the cost of unrelieved pain to the American economy is approximately $110 billion each year. To put that into a more local perspective, if this cost is distributed evenly across the population of the United States, the share for Kansas each year is slightly over $1 billion.

This extreme financial and human cost is unnecessary. Research has demonstrated that approximately 90% of individuals with pain can achieve adequate pain control using oral and intravenous pain medications, along with non-drug interventions. We do not approach this level of success in common medical practice. The failure of the healthcare system to provide adequate pain relief to individuals with pain can be traced to a number of sources. From the perspective of healthcare professionals, some of the barriers include inadequate assessment of patients' pain reports; an unwillingness to accept patients' reports of pain as being valid or reliable; fear that prescribing appropriate pain medications will result in addiction or other untoward side effects; inadequate knowledge of available options for treating pain; fear of being sued for overprescribing; and fear of sanction by regulatory and law enforcement agencies. In fact, it is quite possible to obtain adequate education on pain assessment and treatment, given the prevalence of continuing education opportunities available today; addiction as a consequence of pain treatment is a truly rare complication, one that physicians can be taught to prevent, detect, and treat appropriately; physicians are increasingly being sued for undertreatment of pain; and, at least in Kansas, the regulatory and law enforcement communities have demonstrated a commitment to evaluating pain treatment appropriately, such that physicians who make an honest effort to provide good treatment and document that effort appropriately are not subject to sanction.

Still, despite our superb public policy and supportive regulatory boards, available statistics indicate that the quality of pain management in Kansas is below average.

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HB2649 seeks to improve pain care for Kansans by making a strong positive statutory statement on the subject, while simultaneously eliminating the few negative features of our public policy identified by experts in this subject area. Section 2 of this bill outlines a Pain Patient's Bill of Rights, stating in simple terms the Legislature's belief in the basic right of patients to have their pain reports heard, believed, and acted upon appropriately. This recognition of the rights of individuals with pain is consistent with statements from the Joint Commission on the Accreditation of Healthcare Organizations and numerous other professional organizations. The LIFE Project's Pain Management Task Group has used much of the content of this Bill of Rights in its campaign, and as such, it has been reviewed and approved by a variety of our partner organizations, as we jointly try to improve the care of patients with life-limiting illnesses. It also closely mirrors the content of a Pain Patient's Bill of Rights developed by the American Pain Foundation. HB2649 puts this right into practical terms, outlining the type of treatment individuals with pain should expect when they see a healthcare professional. By stating these rights in this form, they are given statutory authority, and it is made perfectly clear that the Legislature believes that patients with pain should expect competent and compassionate treatment.

Section 5 of this bill seeks to delete a reference to what is known as the Principle of Double Effect, now contained in our laws prohibiting assisted suicide. The statement of this principle, intended here to reassure physicians that appropriate pain management will not be construed to be assisted suicide, in fact provides no actual protection, and instead reinforces the inaccurate notion that patients are at grave risk of being inadvertently killed when pain is managed appropriately. Current medical research refutes this notion. Eliminating the clauses indicated in the bill does absolutely nothing to change the meaning and enforceability of the existing laws; in both cases, it is still the *intent* of the physician that is the crux of the matter.

Finally, section 6 of the bill is an attempt to provide a clearer, more objective definition of unprofessional conduct as it relates to prescribing, dispensing, administering, or distributing medications, especially with respect to the controlled substances used to treat pain. This revision reflects the sentiments expressed in guidelines for the use of controlled substances in the treatment of pain, as issued by not only the Kansas State Board of Healing Arts, but also by the Kansas State Board of Nursing, and jointly by the Boards of Healing Arts, Nursing, and Pharmacy. Note that the bill's language not only defines "excessive" by referencing "all the medical facts relating to the patient", but it further reinforces the ability of the Board of Healing Arts to hold physicians accountable for "inadequate" treatment of pain. The importance of insuring that healthcare professionals understand that undertreatment of pain carries the same potential professional consequences as the overtreatment of pain can not be overstated, and it reflects language contained in both the joint statement of the licensing boards referenced earlier, and the recent Model Policy for the Use of Controlled Substances in the Treatment of Pain, as issued by the Federation of State Medical Boards.

It is my sincere hope that you will carefully consider this important topic and act to promote the relief of pain for all Kansans by adopting HB2649. Thank you very much for the opportunity to speak to you in support of it today.

Kansas Society of Anesthesiologist

Remarks Concerning House Bill No. 2649

Senate Public Health and Welfare Committee

March 16, 2006

Senator Barnett and Members of the Senate Committee:

Thank you for the opportunity to present testimony in favor of HB 2649. I am Doug Smith and I am offering remarks on behalf of the Kansas Society of Anesthesiologist.

An anesthesiologist is a medical physician who specializes in the field of anesthesiology, the science (and art) of preventing or relieving pain. After four-year college program, four years of graduate doctoral training (medical school), an anesthesiologist must complete a one-year term internship and then three years of training in the medical specialty of anesthesiology and pain medicine (an anesthesia residency). After fulfilling specific requirements set by the American Board of Anesthesiology and passing two rigorous examinations, an anesthesiologist earns Board Certification in anesthesia.

The role of an anesthesiologist extends beyond the operating room and recovery room. Anesthesiologists work in intensive care units to help restore critically ill patients to stable condition. In childbirth, anesthesiologists manage the care of two persons: they provide pain relief for the mother while managing the life functions of both the mother and the baby. Anesthesiologists also specialize in pain management, including diagnosis and treatment of acute and chronic problems.

House Bill No. 2649 enacts the Pain Patient's Bill of Rights. The bill provides patients suffering from pain with certain expectations in regard to the care and treatment they receive. When the original draft of the bill came out, our members had concerns about the potential for unreasonable expectations and the possibility of unintended consequences by legislating the physician – patient relationship.

Members of the House Health and Human Services Committee adopted amendments which have clarified language and satisfied our concerns.

We appreciate your consideration of this legislation and encourage your favorable action on House Bill No. 2649.

Thank you for your time this afternoon.

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Senator Barnett:

Members: Public Health and Welfare Committee
March 16, 2006

Regarding HB 2649, the "Pain Patients Bill of Rights"

I am an interventional pain management physician practicing in Wichita Kansas. I am board certified in Anesthesiology, with added qualifications and certification in Pain Management. I am a Fellow of Interventional Pain Practice by the World Congress of Pain. I currently sit on the CMS carrier advisory committee for Kansas, Nebraska and Western Missouri representing the specialty of Interventional Pain Management. I have also been certified in Addiction Medicine by the American Society of Addiction Medicine and at one time served as the medical director of an inpatient Alcohol and Drug treatment Program. I have also served as Chair of the Department of Anesthesiology at Via Christi-St Francis in Wichita. Currently I am the Medical Director of Midwest Surgery Center and the CEO of Pain Management Associates, L.C. in Wichita.

My great concern centers on the premises of HB 2649 that chronic non-cancer pain can be well treated with ever increasing doses of narcotics. This is simply not true. The idea that patients be treated with care, concern and sound medical judgment is not new to any Kansas physician. We must remember our pledge to "do no harm". To legislate an entitled class of patients that bypass sound medical judgment would allow progression to the demand prescribing of controlled substances. This is not in the interest of improving health care or health care access in Kansas. Once, identified by the health care system these patients would be forgotten in the narcotic fog that would surround them.

Imagine the nightmare that would ensure when patients enter the ER on a Saturday night demanding to be treated for pain with narcotics and refusing any and all diagnostic or therapeutic interventions. Nearly every recommendation on the prescribing of narcotics requires oversight and continued medical judgment. This bill would lead to incredible law enforcement issues and must be evaluated as it relates to Federal Narcotic laws.

Recently in Wichita, a family physician was charged with improper prescribing practices and is undergoing investigation by the DEA and others. This bill would essentially condone and encourage widespread controlled substance prescribing practice with much less oversight and control than were evident in this practice.

Although HB 2649 was initially drafted to improve access to adequate pain relief for terminal cancer and dying patients, its application to non-malignant pain patients as well as many caner patients is misdirected The article which you have before you discusses many issues which I would ask you to carefully consider as they relate to HB 2649.

Thank you for the opportunity to express my opinion in this matter:

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Senate Public Health & Welfare Committee
Date: March 16, 2006
Attachment # 13

Pain Physician. 2006;9:1-40, ISSN 1533-3159

Opioid Guidelines

Opioid Guidelines in the Management of Chronic Non-Cancer Pain

Andrea M. Trescot, MD, Mark V. Boswell, MD, Sairam L. Atluri, MD, Hans C. Hansen, MD, Timothy R. Deer, MD, Salahadin Abdi, MD, Joseph F. Jasper, MD, Vijay Singh, MD, Arthur E. Jordan, MD, Benjamin W. Johnson, MD, Roger S. Ocala, MD, Elmer E. Dunbar, MD, Standiford Helm II, MD, Kenneth G. Varley, MD, P.K. Suchdev, MD, John R. Swicegood, MD, Aaron K. Calodney, MD, Bentley A. Ogoke, MD, W. Stephen Minore, MD, and Laxmaiah Manchikanti, MD

Background: Opioid abuse has increased at an alarming rate. However, available evidence suggests a wide variance in the use of opioids, as documented by different medical specialties, medical boards, advocacy groups, and the Drug Enforcement Administration (DEA).

Objectives: The objective of these opioid guidelines by the American Society of Interventional Pain Physicians (ASIPP) is to provide guidance for the use of opioids for the treatment of chronic non-cancer pain, to bring consistency in opioid philosophy among the many diverse groups involved, to improve the treatment of chronic non-cancer pain, and to reduce the incidence of drug diversion.

Design: A policy committee evaluated a systematic review of the available literature regarding opioid use in managing chronic non-cancer pain. This resulted in the formulation of the essentials of guidelines, a series of potential evidence linkages representing conclusions, followed by statements regarding relationships between clinical interventions and outcomes.

Methods: Consistent with the Agency for Healthcare Research and Quality (AHRQ) hierarchical and comprehensive standards, the elements of the guideline preparation process included literature searches, literature synthesis, systematic review, consensus evaluation, open forum presentations, formal endorsement by the Board of Directors of the American Society of Interventional Pain Physicians (ASIPP), and blinded peer review. Evidence was designated based on scientific merit as Level I (conclusive), Level II (strong), Level III (moderate), Level IV (limited), or Level V (indeterminate).

Results: After an extensive review and analysis of the literature, the authors utilized two systematic reviews, two narrative reviews, 32 studies included in prior systematic reviews, and 10 additional studies in the synthesis of evidence. The evidence was limited.

Conclusion: These guidelines evaluated the evidence for the use of opioids in the management of chronic non-cancer pain and recommendations for management. These guidelines are based on the best available scientific evidence and do not constitute inflexible treatment recommendations. Because of the changing body of evidence, this document is not intended to be a "standard of care."

Key Words: Chronic pain, persistent pain, controlled substances, substance abuse, dependency, prescription accountability, opioids, prescription monitoring, diversion, guidelines

CONTENTS

From: American Society of Interventional Pain Physicians, Paducah, KY
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Conflict of Interest: None
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1.0 Introduction

1.1 Purpose

Guidelines for the use of opioids in the treatment of chronic non-cancer pain are statements developed by the American Society of Interventional Pain Physicians (ASIPP) to improve quality and appropriateness of care, improve patient access, improve patient quality of life, improve efficiency and effectiveness, minimize abuse and diversion, and achieve cost containment by improving the cost-benefit ratio.

1.2 Rationale and Importance

Available evidence documents a wide degree of variance in the prescribing patterns of physicians in regard to opioids for chronic pain, as suggested by different specialties, medical boards, advocacy groups, and the Drug Enforcement Administration (DEA).

Opioids are commonly used in managing chronic non-cancer pain, even though this practice is controversial (1-3). However, documented abuse of opioids is increasing at an alarming rate (4-11). While speaking at ASIPP's 2004 annual meeting in Washington, DC, Patricia Good of the DEA's Drug Diversion Control division, stated that the United States, with 4.6% of the world's population, uses 80% of the world's opioids.

Interventional pain management, as defined by the National Uniform Claims Committee (NUCC), is the discipline of medicine devoted to the diagnosis and treatment of pain and related disorders, with the application of interventional techniques to manage subacute, chronic, persistent, and intractable pain, independently or in conjunction with other modalities of treatments. Multidisciplinary or comprehensive pain management differs among specialties and may elicit confusion. An interventionalist perceives comprehensive treatment programs as programs with interventional techniques as the primary treatment modality, with physical therapy, medical therapy, and psychological management as supplementary.

1.3 Objectives and Benefits

The objectives of these guidelines are to bring consistency in opioid prescribing to the many diverse groups involved; to provide analysis of evidence to treat a chronic pain patient with opioids, thus, maintaining reasonable patient access while reducing the risk of drug diversion; to provide practical prescribing guidelines for physicians to reduce the risk of legal and regulatory sanctions; and to emphasize the need for systematic evaluation and ongoing care of patients with chronic or persistent pain.

The perceived benefits of these guidelines include:

- Improved patient compliance
- Improved patient care with appropriate medical management
- Reduced misconceptions among providers and patients about opioids
- Improved ability to manage patient expectations
- Reduced abuse and diversion
- Improved cooperation among patients, providers, and regulatory agencies.

1.4 Population and Preferences

The population covered by these guidelines includes all patients suffering with chronic non-cancer pain who may be eligible for appropriate, medically-necessary management. This management may include, or be independent of, interventional techniques.

1.5 Implementation and Review

The dates for implementation and review were established:

- Effective date – February 1, 2006
- Scheduled review - July 1, 2007
- Expiration date – January 31, 2008

1.6 Application

These guidelines are primarily intended for use by interventional pain physicians. Others managing chronic pain patients with opioids may also find these guidelines useful.

These guidelines do not constitute inflexible treatment recommendations. It is expected that a provider will establish a plan of care on a case-by-case basis, taking into account an individual patient's medical condition, personal needs, and preferences, as well as the physician's experience. Based on an individual patient's needs, treatment different from that outlined here could be warranted. These guidelines do not represent a "standard of care."

1.7 Focus

These guidelines focus on the effective management of chronic non-cancer pain as well as the multiple issues related to opioid administration. It is recognized that management of chronic non-cancer pain takes place in a wide context of healthcare involving multiple specialists and multiple techniques. Consequently, the decision to implement a particular management approach should be based on a comprehensive assessment of the patient's overall health status, disease state, patient preference, and physician training and skill.

1.8 Methodology

In developing these guidelines, evidence-based approaches were given the highest priority. If evidence-based approaches failed to give acceptable levels of information consensus, expert opinions were utilized. These approaches are described in separate publications (12-16).

A policy committee was convened and included a broad representation of academic and clinical practitioners recognized as experts in one or more aspects of opioids, and representing a variety of practices and geographic areas. This committee formalized the essentials of the guidelines. This was followed by the formulation of a series of potential evidence linkages representing conclusions and statements about relationships between clinical interventions and outcomes. The elements of the guideline preparation process included literature searches, literature syntheses, systematic review, consensus evaluation, open forum presentations, formal endorsement by the ASIPP Board of Directors and blinded peer review.

In synthesizing the evidence, systematic reviews, randomized clinical trials, and observational studies were evaluated utilizing reporting criteria and quality evaluation criteria (13,14, 17-19). Details of evidence synthesis are described in multiple publications (13,16,17). If the available systematic reviews met the criteria of inclusion, only those studies published after the publication date of the systematic reviews were evaluated.

While an evidence-based approach may seem to enhance the scientific rigor of guideline development, recommendations may not always meet the highest scientific standards (13-15). Evidence-based medicine is defined as the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients (16).

In the preparation of these guidelines, it is recognized that at the core of an evidence-based approach to clinical or public health issues is, inevitably, the evidence itself, which needs to be carefully gathered and collated from a systematic literature review of the particular issues. Consequently, the process by which the strength of scientific evidence is evaluated in the development of evidence-based medicine recommendations and guidelines is crucial. The practice of evidence-based medicine requires the integration of individual clinical expertise with the best available clinical evidence from systematic research.

Systems for grading the strength of a body of evidence are much less uniform and consistent than are those for rating study quality. Consequently, the guideline committee designed levels of evidence from Level I through Level V, modified from various publications (Table 1) (13,17).

Table 1. *Designation of levels of evidence*

Level I	Conclusive: Research-based evidence with multiple relevant and high-quality scientific studies or consistent reviews of meta-analyses
Level II	Strong: Research-based evidence from at least one properly designed randomized, controlled trial; or research-based evidence from multiple properly designed studies of smaller size; or multiple low quality trials
Level III	Moderate: a) Evidence obtained from well-designed pseudorandomized controlled trials (alternate allocation or some other method); b) evidence obtained from comparative studies with concurrent controls and allocation not randomized (cohort studies, case-controlled studies, or interrupted time series with a control group); c) evidence obtained from comparative studies with historical control, two or more single-arm studies, or interrupted time series without a parallel control group.
Level IV	Limited: Evidence from well-designed nonexperimental studies from more than one center or research group; or conflicting evidence with inconsistent findings in multiple trials
Level V	Indeterminate: Opinions of respected authorities, based on clinical evidence, descriptive studies, or reports of expert committees

Reproduced from Boswell et al (12) *Interventional techniques in the management of chronic spinal pain: Evidence-based practice guidelines*; with permission from the authors and the American Society of Interventional Pain Physicians.

2.0 Chronic Pain

2.1 Definitions

Chronic pain has numerous definitions. Consequently, a combination of multiple definitions can be utilized (12):

- Pain that persists beyond the usual course of an acute disease or a reasonable time for any injury to heal that is associated with chronic pathologic processes that cause continuous pain or pain at intervals for months or years
- Persistent pain that is not amenable to routine pain control methods
- Pain where healing may never occur

Pain is a highly disagreeable sensation that results from an extraordinarily complex and interactive series of mechanisms integrated at all levels of the neuraxis, from the periphery to higher cortical structures.

2.2 Prevalence

The prevalence of chronic pain in the adult population ranges from 2% to 40%, with a median point prevalence of 15% (12,20,21). Persistent pain was reported with an overall prevalence of 20% of primary care patients, with approximately 48% reporting back pain (22). The literature also has consistently described the high prevalence of chronic pain in children and the elderly (23-28). In addition, chronic pain with involvement of multiple regions is a common occurrence in over 60% of patients (24).

2.3 Chronicity

Duration of pain and its chronicity have been topics of controversy. Conventional beliefs are that most episodes of low back pain will be short-lived, with 80% to 90% of attacks resolving in about 6 weeks irrespective of the administration or type of treatment, and with 5% to 10% of patients developing persistent back pain. However, this concept has been questioned as the condition tends to relapse and most patients will experience recurrent episodes. Modern evidence has shown that chronic persistent low back pain and neck pain in children and adults are seen in up to 60% of patients, 5 years or longer after the initial episode (12,23,29-35).

2.4 Health and Economic Impact

Chronic non-cancer pain is associated with significant economic, societal, and health impact (36-49). The cost of uncontrolled chronic pain is enormous

both, to individuals and to society as it leads to a decline in quality of life and disability (39,41-49). Estimates and patterns of direct healthcare expenditures among individuals with back pain in the United States reached $90.7 billion for the year 1998 (39). On average, individuals with back pain generate healthcare expenditures about 60% higher than do individuals without back pain ($3,498 per year versus $2,178). It was estimated that the cost of healthcare for patients with chronic pain might exceed the combined cost of treating patients with coronary artery disease, cancer, and AIDS (45). In the United States, it was estimated that the cost of treatment in the first year after failed back surgery for pain was approximately $18,883 in 1997 (46). Even further, annual healthcare cost incurred by chronic pain patients, excluding cost for surgical procedures, may range from $500 to as high as $35,400, with averages ranging from $12,900 to $18,883 annually (46,47).

3.0 Opioids in Chronic Pain

3.1 General Considerations

Considerable controversy exists about the use of opioids for treatment of chronic pain of non-cancer origin. Inadequate treatment of pain has been attributed to a lack of knowledge about pain management options, inadequate understanding of addiction, or to fears of investigation or sanction by federal, state, and local regulatory agencies (2,3,50-73). Many authors contend that drug therapy with opioid analgesics plays an important role in pain management and should be available when needed for the treatment of all kinds of pain, including non-cancer pain (50,52-55,64-69) . The DEA also took the position that 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 (70).

3.2 Response to undertreatment

The alleged undertreatment of pain as a major health problem in the United States led to the development of initiatives to address the multiple alleged barriers responsible for the undertreatment of pain (50). Patient advocacy groups and professional organizations have been formed with a focus on improving the management of pain (50). Consequently, numerous clinical guidelines also have been developed, even though none of them have been developed using evidence-based medicine.

In 1998 and 2004, to alleviate physician uncertainty about opioid use and to encourage better pain control, the Federation of State Medical Boards (FSMB) issued model guidelines or policies for the use of controlled substances for the treatment of pain (73). Over half of the state medical boards either adapted or modified these guidelines and implemented them in their states. In addition, based on the influence of advocacy groups, over one-third of the state legislatures have instituted intractable pain treatment acts that provide immunity from discipline for physicians who prescribe opioids within the requirements of the statute. However, the guidelines, policies, and legislative actions sometimes have been criticized as having created new barriers to appropriate pain management.

3.3 Opioid Use in Chronic Pain

In pain management settings, as many as 90% of patients have been reported to receive opioids for chronic pain management (74-93). A prospective evaluation (74) showed that 90% of the patients were on opioids and 42% were on benzodiazepines prior to presenting to an interventional pain management center. Many of the patients also received more than one type of opioid, most commonly one for sustained release and one for breakthrough pain. The frequency of overall opioid use among patients with back pain was reported as approximately 12% (94). It was found that rheumatologists, family practitioners, and internists were much more likely to prescribe opioids for patients with chronic pain than were surgeons and neurologists (48,95). A cross-sectional analysis of analgesic use by patients with low back pain, showed that in 2001, 55.5% of insurance plan members with low back pain had insurance claims for analgesics, with 68% of those claimants receiving an opioid (96). Further, Medicaid patients were more likely to receive prescription drugs, particularly opioids (73% Medicaid vs 40% commercial insurance), for 30 days or longer and to visit the emergency room more frequently (97). Multiple other reports (98-114) revealed widespread use of opioids in the management of chronic pain. Finally, the increasing retail sale of opioid medications is the proof that opioids are used much more frequently (Table 2). Retail sales of opioid medications represented as grams of medication increased significantly from 1997 to 2002 (106-108). Illicit drug use and dose escalations have been demonstrated in a similar proportion of patients on long-acting and short-acting opioids (78,79).

Table 2. *Retail sales of opioid medications (grams of medication) 1997-2002*

	1997	2002	% change
Morphine	5,922,872	10,264,264	73.3
Hydrocodone	8,669,311	18,822,618	117.1
Oxycodone	4,449,562	22,376,891	402.9
Methadone	518,737	2,649,559	410.8

3.4 Non-Medical Use of Prescription Drugs

3.4.1 Center on Addiction and Substance Abuse (CASA) Findings

Joseph A. Califano, Jr., Chairman and President of the National Center on Addiction and Substance Abuse at Columbia University (CASA), in a July 2005 editorial on the Diversion and Abuse of Controlled Prescription Drugs in the United States (4) noted the following:

"While America has been congratulating itself in recent years on curbing increases in alcohol and illicit drug abuse and in the decline in teen smoking, abuse and addiction of controlled prescription drugs – opioids, central nervous system depressant and stimulants – have been stealthily, but sharply, rising. Between 1992 and 2003, while the U.S. population increased 14%, the number of people abusing controlled prescription drugs jumped 94% – twice the increase in the number of people abusing marijuana, five times in the number abusing cocaine and 60 times the increase in the number abusing heroin. Controlled prescription drugs

like OxyContin®, Ritalin®, and Valium® are now the fourth most abused substances in America behind only marijuana, alcohol, and tobacco[3].

The CASA report (4) presented alarming statistics including a 212% increase from 1992 to 2003 in the number of 12- to 17-year-olds abusing controlled prescription drugs, and the increasing number of teens trying these drugs for the first time. The report also illustrated that new abuse of prescription opioids among teens is up an astounding 542%, more than four times the rate of increase among adults. Furthermore, disturbing statistics also show that teens who abuse opioids are likely to use other drugs including alcohol, marijuana, heroin, ecstasy, and cocaine at rates respectively of 2, 5, 12, 15, and 21 times that of teens who do not abuse such drugs.

As per the CASA report (4), the bottom line is that the United States is in the throes of an epidemic of controlled prescription drug abuse and addiction with 15.1 million people admitting to abusing prescription drugs – more than the combined number of those who admit abusing cocaine (5.9 million), hallucinogens (4 million), inhalants (2.1 million), and heroin (0.3 million).

3.4.2 Physician Survey Highlights

A CASA survey of 979 physicians regarding the diversion and abuse of controlled prescription drugs showed the following:

- Physicians perceive the three main mechanisms of diversion to be
  - Doctor shopping (when patients obtain controlled drugs from multiple doctors) (96.4%)
  - Patient deception or manipulation of doctors (87.8%)
  - Forged or altered prescriptions (69.4%).
- 59.1% believe that patients account for the bulk of the diversion problem.
- 47.1% said that patients often try to pressure them into prescribing a controlled drug.
- Only 19.1% of surveyed physicians received any medical school training in identifying prescription drug diversion.
- Only 39.6% received any training in medical school in identifying prescription drug abuse and addiction.
- 43.3% of physicians do not ask about prescription drug abuse when taking a patient's health history.
- 33% do not regularly call or obtain records from the patient's previous (or other treating) physician before prescribing controlled drugs on a long-term basis. HIPPA regulations have made this step much more difficult.
- 74.1% have refrained from prescribing controlled drugs during the past 12 months because of concern that a patient might become addicted to them.

Table 3. *Past use of illicit drugs and illicit pain relievers among persons age 12 or older; 2003 survey*

	Number (Percentage)			
	12-17 years of age	18-25 years of age	>26 years of age	Total >=12 years
U.S Population	24,995,000	31,728,000	180,958,000	237,682,000
Any illicit drug	5,448,000.9 (21.8%)	10,977,0008 (34.6%)	18,638,000.7 (10.3%)	34,993,000 (14.7%)
Non-medical use of any psychotherapeuti c drug	2,229,0005 (9.2%)	4,600,0006 (14.5%)	8,143,000 (4.5%)	14,986,000 (6.3%)
Non-medical use of pain relievers	1,924,000.6 (7.7%)	3,807,000.4 (12.0%)	5,971,000.6 (3.3%)	11,671,000 (4.9%)

Source: 2003 SAMHSA Survey (112)

3.4.3 Pharmacist Survey Highlights

A CASA survey of 1,303 pharmacists regarding diversion and abuse of controlled prescription drugs showed the following:

- When a patient presents a prescription for a controlled drug:
  - 78.4% of pharmacists become "somewhat or very" concerned about diversion or abuse when a patient asks for a controlled drug by its brand name;
  - 26.5% "somewhat or very often" think it is for purposes of diversion or abuse.
- 51.8% believe that patients account for the bulk of the diversion problem.
- Only about half of the pharmacists surveyed received any training in identifying prescription drug diversion (48.1%) or abuse or addiction (49.6%) since pharmacy school.
- 61% do not regularly ask if the patient is taking any other controlled drugs when dispensing a controlled medication; 25.8% rarely or never do so.
- 28.9% have experienced a theft or robbery of controlled drugs at their pharmacy within the last five years; 20.9% do not stock certain controlled drugs in order to prevent diversion.
- 28.4% do not regularly validate the prescribing physician's DEA number when dispensing controlled drugs; one in 10 (10.5%) rarely or never do so.
- 83.1% have refused to dispense a controlled drug in the past year because of suspicions of diversion or abuse.

Increasing abuse and diversion of prescription drugs "on the street" are serious problems. A study evaluating severe dependence on oral opioids illustrated that the majority of patients with severe dependence (39%) obtained opioids by going to different physicians (11). Another frequent form of obtaining opioids included "street" purchase by 26% of the patients. This study also showed that many patients used more than one method of acquiring the drugs. In evaluating prescription opioid abuse in patients presenting for methadone maintenance treatment (10), at admission most patients (83%) had been using prescription opioids with or without heroin. This study showed that 24% had used prescription opioids only, 24% used prescription opioids initially and heroin later, 35% used heroin first and prescription opioids subsequently, and 17% had used heroin only. Subjects reported regular use of prescription opioids at higher than therapeutic doses. In 2001, prescription drug abuse and misuse was estimated to impose approximately $100 billion annually in health care costs (9,110,111). The abuse of prescription medications has increased steadily over the last 10 years, and every year more and more Americans try them for the first time. The abuse of controlled prescription drugs was foreshadowed by dramatic increases in their manufacture and distribution and the number of prescriptions written and filled (106-108). Between 1992 and 2002, while the population of the United States increased by 13% and the number of prescriptions written for non-controlled drugs increased by 57%, the number of prescriptions filled for controlled drugs increased by 154%. During this same period, there was a 90% increase (from 7.8 million to

14.8 million) in the number of people who admitted abusing controlled prescription drugs (4).

3.4.4 Substance Abuse and Mental Health Services Administration (SAMHSA) Survey

The SAMHSA 2003 survey of drug abuse(112) revealed that 6.3% of the U.S populaceover 12 years of age (14,966,000 individuals) used psychotherapeutic drugs for non-medical purposes; of these, 4.9% of theU.S population(11,671,000 individuals) over 12 years of age used pain relievers for non-medical purposes during the past year (Table 3, p 5). The number of individuals abusing pain medications for the first time grew from 628,000 in 1990 to nearly 3 million in 2000 (Fig. 1, p XX). First-time use of stimulants and tranquilizers is also on therise. Increases for specific opioids are illustrated in Table 3, with the highest increase that of oxycodone at 345% (106-108).

3.4.5 Drug Abuse Warning Network (DAWN) Reports

Drug-related emergency department visits also reveal that prescription drug abuse is on the rise (Fig. 2) (107,108). From 1994 to 2002, mentions of pain medications during emergency department visits increased by 168%, while mentions of benzodiazepines increased by 42%.

During the same time period, the percentage of increase mentioned by the Drug Abuse Warning Network (DAWN) for prescription pain relievers has been greater than the percentage of increase for marijuana, cocaine, and heroin.

3.5 Substance Abuse in Chronic Pain

It has been reported that the principle drug of abuse for nearly 10% of youths in drug treatment programs is a prescription drug (115). In a comprehensive review (80), between 3.2% and 18.9% of patients were found to have been diagnosed with a substance abuse disorder. In addition, it was also concluded that diagnoses of abuse, drug dependency, and drug addiction occur in a significant proportion of chronic pain patients.

While opioids are by far the most abused drugs, other controlled substances such as benzodiazepines, sedative hypnotics, and central nervous system stimulants, though described as having less potential for abuse, are also of major concern to interventional pain specialists as they appear to be widely used for non-medical purposes as well (106-108,112). This is exemplified by the fact that benzodiazepine-related emergency department visits increased from 71,609 in 1995 to 100,784 in 2002 (108). Further, it has been reported that 77.3% of suicide attempts involved benzodiazepines (114).

Multiple investigators (81-85,116-119) have shown a prevalence of drug abuse in 18% to 41% in patients receiving opioids for chronic pain. A study evaluating the prevalence, comorbidities and utilization of opioid abuse in a cohort of managed care patients with matched controls showed that opioid abuse rose from 2000 to 2002 (105). The authors concluded that opioid abuse was 6.7 per 10,000 patients in 2002. Opioid abusers also presented with higher prevalence of opioid prescriptions and comorbidities as compared to controls.

Illicit drug use is also a common phenomenonin chronic pain patients. Table 4 illustrates the prevalence of prescription drug abuse in a typical interventional pain management practice setting. Illicit drug use without controlled substance abuse was found in 14% to 16% of patients, and illicit drug use in patients with controlled substance abuse was present in 34% of the patients (120,121). Based on their type of insurance, the prevalence of illicit drug use among individuals with chronic pain was shown to be highest in patients on Medicaid (98) (Table 5). Others (87,122) also showed significant illicit drug use in patients with chronic non-

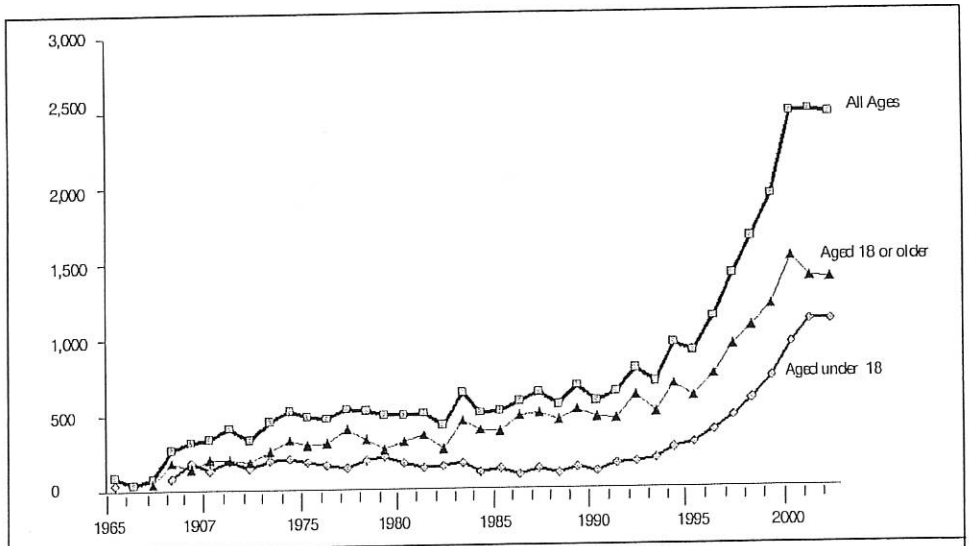

Fig. 1. *Annual numbers of new non-medical users of pain relievers: 1965-2002*
Adapted from Ref. 112.

malignant pain treated with opioids.

Overall use and abuse of opioids and other controlled substances in conjunction with illicit drug use appears to be prevalent in pain management settings (86,87,120-124). Advocacy and unproven Joint Commission standards may be leading to the overuse of opioids and subsequent abuse. At the same time Americans continue to be dissatisfied with their pain relief options.

3.6 Economic Impact

In 1995, the Center on Addiction and Substance Abuse (CASA) estimated the costs of substance abuse to federal entitlement programs and found that

Table 4. *Prevalence of controlled prescription drug abuse in an interventional pain practice*

	Total of 500 patients	Proportion
Grade '0' – No abuse	444	72.2%
Grade I – Low grade abuse	47	9.4%
Grade II – Moderate abuse – 3 or more physicians – Receiving Schedule II drugs – Abusing Schedule II drugs	30	6%
Grade III – High grade abuse– Trafficking– Overdose	12	2.4%
Total Abuse	89	17.8%

Modified from Manchikanti et al (84)

Table 5. *Prevalence of illicit drug use in an interventional pain practice*

	Group I (100) Third party	Group II (100) Medicare with or without third party	Group III (100) Medicare & Medicaid	Group IV (100) Medicaid	P Value
Cocaine	7%	4%	6%	8%	0.684
95% CI	2% - 12%	0% - 8%	1% - 11%	3% - 13%	
Marijuana (THC)	11%	8%	20%[b]	34%[a,b,c]	0.0000
95% CI	5% - 17%	3% - 13%	12% - 28%	25% - 43%	
Methamphetamine/Amphetamine	3%	2%	4%	3%	0.876
95% CI	0% - 6%	0% - 5%	0% - 8%	0% - 6%	
Total	17%	10%	24%[b]	39%[a,b,c]	0.0000
95% CI	10% - 24%	4% - 6%	16% - 32%	29% - 49%	

Totals may not correlate as some patients were included in more than one category
CI = Confidence Interval a: Indicates significant difference with Group I b: Indicates significant difference with Group II
c: Indicates significant difference with Group III
Adapted from Manchikanti et al (86)

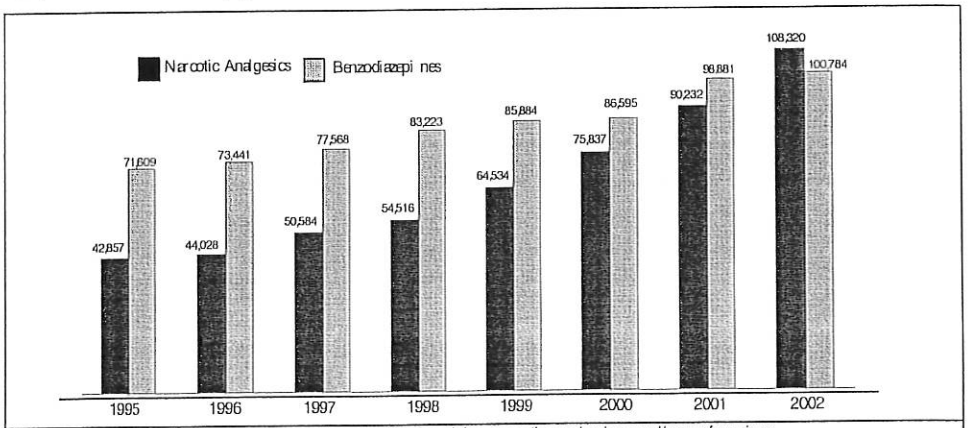

Fig. 2. *Drug abuse related emergency department visits involving narcotic analgesics and benzodiazepines*
Adapted from Ref. 107, 108

health care and disability cost alone were $77.6 billion, representing nearly 20% of the $430 billion health care budget (125). A study by the Office of Management and Budget estimated drug abuse costs to the United States government at $300 billion a year, including government anti-drug programs and the cost of the crime, healthcare (public and nonpublic), accidents, and lost productivity (126). In the Aid to Families with Dependent Children (AFDC), Medicaid and food stamp programs, the incidence of drug abuse varies from 9.4% to 16.4% (127).

3.7 Drug Diversion

Drugs can be diverted from their lawful purpose to illicit use at any point in the pharmaceutical manufacturing and distribution process. The diversion of prescription drugs among adults is typically described to occur through one of the following: doctor shopping, illegal Internet pharmacies, drug theft, prescription forgery, and illicit prescriptions by physicians. Youths typically acquire drugs by stealing from their relatives or buying from classmates who sell their legitimate prescriptions.

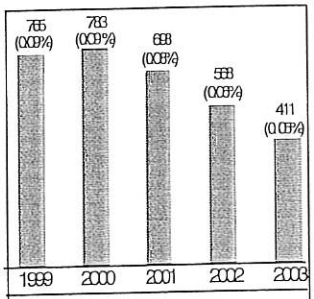

Fig. 3. *Drug Enforcement Administration (DEA) actions against physicians*

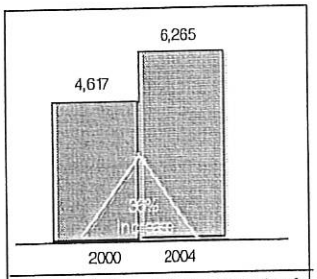

Fig. 4. *Actions by state boards of medical licensure*
Source FSMB (145)

"Doctor shopping" is one of the most common methods of obtaining prescription drugs for legal and illegal use (9,11,78,79,8 3,84,86,87,121,1 22,128,129). The majority of physicians perceive "doctor shopping" as the major mechanism of diversion (4). Doctor shopping typically involves an individual going to several different doctors complaining of a wide array of symptoms in order to get prescriptions. This type of diversion can also involve individuals who use people with legitimate medical needs, like cancer patients, to go to various physicians in several cities to get prescription medications. Patients practicing doctor shopping may target physicians who readily dispense prescriptions without thorough examinations or screening. Some patients with a legitimate medical condition may get prescriptions from multiple physicians in various states or in the same state (9). It has been reported that individuals may collect thousands of pills during a one year period and sell them on the street (9).

Since 1999, illegal Internet pharmacies have provided a convenient alternative for individuals wishing to fill their prescriptions (9,130-132). In 2003, the Federal Drug Administration (FDA) estimated the number of Internet pharmacies selling drugs illegally to be about 400, with approximately 50% of the pharmacies located outside the United States (130). Rogue sites, many under the guise of a legitimate pharmacy, provide controlled substances to people without prescriptions. This is particularly troubling with respect to the 30 million youth nationwide with Internet access (9). There are numerous concerns regarding rogue Internet pharmacies, such as the ability to evade state licensing requirements and standards; dispensing controlled substances without a prescription; and providing fake substandard or inappropriate medication (130). However, state and federal laws governing traditional pharmacy stores apply to Internet sales, regardless of the method used by an Internet pharmacy to dispense the medication.

Prescription drug theft can occur at any point from manufacturer to the patient. Thefts are on the rise, largely due to drastic increases in prescription drug abuse and high street prices (9,131-138). Several drugs ranging from OxyContin to Soma have been implicated. Prescription forgery is also fairly common, either by altering the prescription or stealing blank prescription pads in order to write fake prescriptions (4,9,125,135,139). Prescription forgery may occur in two ways, either by stealing blank prescription pads or by making false prescription blanks or pads in order to write fake prescriptions (9). However, legitimate prescriptions may be altered typically to increase the quantity of controlled substances. Similarly, pharmacists may get involved in prescription drug diversion, first by selling the controlled substances and then, using their database of physicians and patients to write and forge prescriptions to cover their illegal sale. However, the vast majority of prescription forgery is from non-healthcare professionals.

Illicit prescriptions written by physicians, though rare, are a real phenomenon. Making the headlines are criminal cases involving physicians who become involved in diverting prescription drugs for huge profits (9,140-143). However, malprescribing, either due to lack of knowledge or due to prescribing inappropriately through "pill mills," is more common (141-147). Malprescribing often represents a lack of knowledge rather than a deliberate attempt to profit from writing these transactions. Adverse actions taken by the DEA against physician prescribers has, in fact, decreased from 0.9% in 1999 to 0.05% in 2003 (Fig. 3). However, actions by medical licensure boards have been increasing (Fig. 4). Figure 4 illustrates all types of actions, whereas Figure 3, illustrates actions related to controlled substances.

3.8 Controlling Diversion and Abuse

Federal, state, and local governments, as well as professional associations and pharmaceutical companies, share responsibility for preventing diversion and abuse of controlled prescription drugs (4). However, the challenge is to eliminate or significantly curtail diversion and abuse of controlled prescription drugs while assuring proper treatment of patients who can be helped by these medications. Gaps exist between current efforts to control diversion and efforts to maintain access to patient care. These gaps involve international law, federal laws and regulations, activities of the DEA and FDA, scheduling drugs, drug refills, state laws and regulations, and existing prescription drug monitoring programs.

3.8.1 Drug Enforcement Administration

The DEA, as an agency within the United States Department of Justice, is the lead federal law enforcement agency responsible for enforcing the Controlled Substance Act. In cooperation with state authorities and other federal agencies, the DEA is responsible for preventing the diversion of controlled substances for illicit purposes. However, the DEA must comply with international treaties to the extent that they are not in conflict with constitutional provisions; it must also work closely with foreign, state, and local governments. The DEA has increased its monitoring of Internet prescription drug sales. DEA investigations, enforcement, and intelligence programs have started to work more closely with other federal, state, and local agencies to target individuals and organizations involved in diversion and abuse of controlled prescription drugs.

3.8.2 State Laws and Regulations

Every state has professional oversight boards that license and discipline members within each profession. Further, the licensing boards for each health care profession have a designated national organization. However, many of these associations have not been proactive in addressing the problems of prescription drug diversion and abuse (4).

3.8.3 Prescription Drug Monitoring Programs

Prescription drug monitoring programs (PDMPs) capture information that may be shared with law enforcement agencies, health care and regulatory agencies, and in some states, health care practitioners, to help identify inappropriate or illegal activities involving controlled prescription drugs. It has been stated that the scrutiny of professional boards and monitoring programs has, in some cases, created fear that legal action will be taken against physicians and pharmacists regarding their prescribing and dispensing practices. As a result, practitioners may under-treat patients or use less appropriate medications that are not covered by a monitoring program.

The United States Government Accountability Office (GAO) conducted a study on state monitoring programs of prescription drugs (7). They concluded that state monitoring programs provide a useful tool to reduce diversion.

The first prescription drug monitoring program (PDMP) was established in California in 1940. The number of states with PDMPs has grown only slightly over the past decade, from 10 in 1992 to 15 in 2002 (Table 6). These 15 programs cover 47% of the nation's population and DEA-registered practitioners, and about 45% of the nation's pharmacies. Since the GAO report on state monitoring systems was published, PDMPs have been increasing gradually (5).

Prescription drug monitoring programs vary as to objectives, design, and operation, even though the primary objective of PDMPs is to assist law enforcement in detecting and preventing drug diversion. In addition to helping law enforcement identify and prevent prescription drug diversion, state programs may include educational objectives to provide information to physicians, pharmacies, and the public. The programs are also highly variable with regards to monitoring scheduled substances from Schedule II to Schedule IV. Only four states – Utah, Nevada, Kentucky, and Idaho – monitor Schedule II to IV drugs, while the majority monitor only Schedule II drugs. Also, the majority of these programs are retroactive with after-the-fact identification of abuse as reported by public health departments, pharmacy boards, and law enforcement; few are available to practitioners in real time and are useful as a prescribing decision tool. The major disadvantage of the programs is lack of interstate communication. Consequently, only a few programs operate proactively, while most operate reactively.

A few states routinely analyze prescription data collected by PDMPs to identify individuals, physicians, or pharmacies that have unusual use, prescribing, or dispensing patterns that may suggest potential drug diversion, abuse, or doctor shopping. However, only three states provide this information proactively to physicians. The GAO report cited many advantages, as well as disadvantages, to PDMPs. States with PDMPs experience considerable reductions in the time and effort required by law enforcement and regulatory investigators to explore leads and the merits of possible drug diversion cases. However, while the presence of a PDMP may

Table 6. *Prescription drug monitoring programs*

State	Year implemented	Controlled substance schedule(s) monitored	Type of monitoring system	Administrative agency
California	1940	II	Electronic and triplicate form	Pharmacy and law enforcement
Hawaii	1943	II	Electronic	Law enforcement
Idaho	1967	II, III and IV	Electronic	Pharmacy board
Illinois	1961	II	Electronic	Public health
Indiana	1995	II	Electronic	Law enforcement
Kentucky	1999	II, III, IV and V	Electronic	Public health
Massachusetts	1992	II	Electronic	Public health
Michigan	1989	II	Single form	Commerce
Nevada	1997	II, III, and IV	Electronic	Pharmacy board and law enforcement
New York	1977	II	Electronic	Public health
Oklahoma	1991	II	Electronic	Law enforcement
Rhode Island	1979	II, III	Electronic	Public health
Texas	1982	II	Electronic	Law enforcement
Utah	1997	II, III, IV, and V	Electronic	Commerce's Licensing Division
Washington	1987	Determined by disciplinary authority	Triplicate form	Public health

Source: National Alliance for Model State Drug Laws. Information current through February 4, 2002. Adapted from Ref. 7

13-10

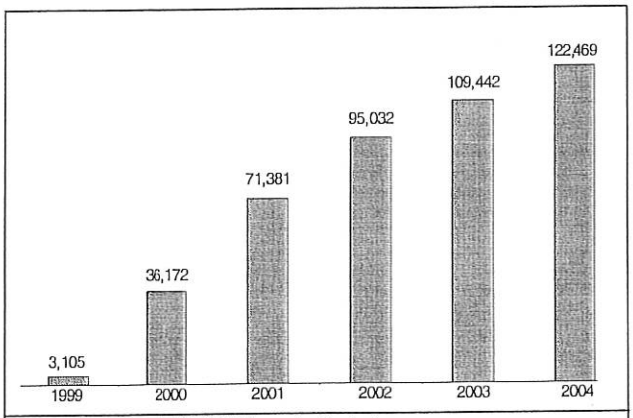

Fig. 5. *Increased KASPER use in Kentucky*
Source: Ref. 138

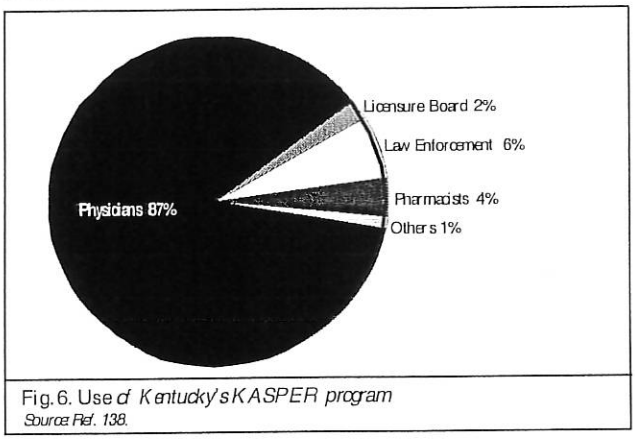

Fig. 6. Use of *Kentucky's KASPER program*
Source: Ref. 138.

help one state reduce its illegal drug diversion, diversion activities may actually increase in contiguous states that do not have PDMPs. All three of the states providing access to physicians – Kentucky, Nevada, and Utah – have helped reduce the unwarranted prescribing and subsequent diversion of abused drugs in their states. In both Kentucky and Nevada, an increasing number of PDMP reports are being used by physicians to check the prescription drug utilization history of current and prospective patients to determine whether it is necessary to prescribe certain drugs that are subject to abuse.

The success of a prescription drug monitoring program can be demonstrated by its use by physicians and other professionals in Kentucky (Fig. 5). Kentucky's KASPER system was designed to produce 2,000 reports per year at its inception in 1999; in 2004, however, it produced in excess of 2,500 reports per week (138). Even then, it is estimated that only 50% of the physicians who prescribe controlled substances in the Commonwealth of Kentucky are using the KASPER system. Further, in Kentucky, 87% of the reports are requested by physicians and 4% by pharmacists. Further, only 6% were requested by law enforcement, and 2% by licensure boards (Fig. 6), dispelling the myth that law enforcement and other regulatory agencies use PDMPs for "witch hunting" physicians.

In addition to multiple state monitoring programs, on August 11, 2005, President Bush signed a new law into effect, enacted by the U.S. Senate and House of Representatives (6). This legislation, named the National All Schedules Prescription Electronic Reporting Act (NASPER), provides for the establishment of a controlled substance monitoring program in each state, with communication between state programs. It tasks the Public Health Service to require the United States Secretary of Health and Human Services to award 1-year grants to each state with an approved application in order to establish, or improve, a state controlled substance monitoring program (1). NASPER was introduced into Congress by the American Society of Interventional Pain Physicians with three major and important goals:

1) Physician and pharmacist access to monitoring programs
2) Monitoring of Schedule II to IV drugs
3) Information sharing across state lines

NASPER was modeled on the highly successful state monitoring program in Kentucky (KASPER) (1).

4.0 Pharmacological Considerations

4.1 Opioid Pharmacology

Opioids are analgesics affecting nociception by modulation of ascending and descending pathways. Opioids may be classified by their function as agonists, mixed agonists-antagonists, or antagonists, as well as by their actions at various opioid receptors.

The opium poppy was cultivated as early as 3400 BC in Mesopotamia. The term opium refers to a mixture of alkaloids from the poppy seed. Opiates are naturally occurring alkaloids such as morphine or codeine. Opioid is the term used broadly to describe all compounds that work at the opioid receptors. The term narcotic (from the Greek word for stupor), originally was used to describe medications for sleep, then was used to describe opioids, but now is a legal term for drugs that are abused.

Morphine (the archetypal opioid) consists of five rings with a phenolic hydroxyl group at Position 3 and an alcoholic hydroxyl group at Position 6 and at the nitrogen atom. Both hydroxyl groups can be converted to ethers or esters. For example, codeine is morphine O-methylated at position 3, while heroin is morphine O-acetylated at positions 3 and 6. Morphine is optically active, and only the levorotatory isomer is an analgesic. The tertiary

Table 7. *Analgesic effects at opioid receptors*

	Mu(μ)	Delta(δ)	*Kappa(κ)*
	• Mu 1 – *Analgesia* • Mu 2 – *Sedation, vomiting, respiratory depression, pruritus, euphoria, anorexia, urinary retention, physical dependence*	• *Analgesia, spinal analgesia*	• *Analgesia, sedation, dyspnea, psychommetic effects, miosis, respiratory depression, euphoria, dysphoria, dyspnea, physical dependence*
Endogenous Peptides			
Enkephalin	*Agonist*	*Agonist*	
β endorphin	*Agonist*	*Agonist*	
Dynorphin A	*Agonist*		*Agonist*
Agonists			
Morphine	*Agonist*		*Weak agonist*
Codeine	*Weak agonist*	*Weak agonist*	
Fentanyl, sufentanil	*Agonist*		
Meperidine	*Agonist*		*Agonist*
Methadone	*Agonist*		
Oxycodone	*Agonist*		*Agonist*
Agonist-antagonists			
Buprenorphine	*Partial agonist*		*Antagonist*
Pentazocine	*Partial agonist*		*Agonist*
Nalbuphine	*Antagonist*		*Agonist*
Butorphanol	*Partial agonist*		*Antagonist*
Nalorphine	*Antagonist*		*Agonist*
Antagonists			
Naloxone	*Antagonist*	*Weak Antagonist*	*Antagonist*
Naltrexone	*Antagonist*	*Weak Antagonist*	*Antagonist*

form of the nitrogen appears to be crucial to the analgesia of morphine; making the nitrogen quaternary greatly decreases the analgesia, since it cannot pass into the central nervous system. Changes to the methyl group on the nitrogen will decrease analgesia as well, creating antagonists such as nalorphine.

4.1.1 Opioid Receptors

There are opioid receptors within the central nervous system (CNS) as well as throughout the peripheral tissues. These receptors are normally stimulated by endogenous peptides (endorphins, enkephalins, and dynorphins) produced in response to noxious stimulation. Greek letters name the opioid receptors, based on their prototype agonists (Table 7).

Mu (μ) (agonist morphine) – Mu receptors found primarily in the brainstem and medial thalamus. Mu receptors are responsible for supraspinal analgesia, respiratory depression, euphoria, sedation, decreased gastrointestinal motility, and physical dependence. Subtypes include Mu1 and Mu2, with Mu1 related to analgesia, euphoria, and serenity, while Mu2 is related to respiratory depression, pruritus, prolactin release, dependence, anorexia, and sedation.

Kappa (κ) (agonist ketocyclazocine) – Kappa receptors found in limbic and other diencephalic areas, brain stem and spinal cord are responsible for spinal analgesia, sedation, dyspnea, dependence, dysphoria, and respiratory depression.

Delta (δ) (agonist delta-alanine-delta-leucine-enkephalin) – Delta receptors restricted largely to the brain are not well studied. They may be responsible for psychomimetric and dysphoric effects.

Sigma (σ) (agonist N-allylnormetazocine) – Sigma receptors are responsible for psychomimetic effects, dysphoria, stress-induced depression. They are no longer considered opioid receptors, but rather the target sites for phencyclidine (PCP) and its analogs.

These opioid receptors, concentrated in the ventral tegmental and periaqueductal grey areas, presynaptically inhibit the transmission of excitatory pathways: acetylcholine, catecholamine, serotonin, and substance P. Activation of the opioid receptor inhibits adenylate cyclase. All opioid receptors are G protein-linked structures embedded in the plasma membrane of neurons; activation releases a portion of the G protein, which moves in the membrane until it reaches its target (either an enzyme or an ion channel). These targets alter protein phosphorylation and/or gene transcription. Opioids and endogenous opioids activate presynaptic receptors on GABA neurons, which inhibit the release of GABA in the ventral tegmental area. This allows dopaminergic neurons to fire more vigorously, and the extra dopamine in the nucleus accumbens is intensely pleasurable. The varying effects of opioids may therefore be related to varying degrees of affinity for the various receptors.

The opioid receptors were discovered in 1972, and the first endogenous opioid (enkephalin) was discovered in 1975. Their location in the CNS allows them to function as neurotransmitters, and they may play a role in hormone secretion, thermoregulation, and cardiovascular control.

Enkephalins are derived from pro-enkephalin and are relatively selective δ ligands.

Endorphins are derived from pro-opiomelanocortin (also the precursor for ACTH and MSH), and bind to the μ receptor.

Dynorphins are derived from pro-dynorphins, and are highly selective at the μ receptors.

Nociceptin (orphanin), identified in 1995, may have potent hyperalgesic effects. It has little affinity for the μ, δ, or κ receptors. Nociceptin antagonists may be antidepressants and analgesics.

Pure opioid agonists (e.g., morphine, hydromorphone, fentanyl) stimulate μ receptors and are the most potent analgesics. As the dose is increased, analgesia occurs in a log linear fashion; the degree of analgesia induced is limited only by intolerable dose-related adverse effects. In contrast, opioid agonists/antagonists and opioid partial agonists (buprenorphine, pentazocine, nalbuphine, butorphanol, nalorphine) exhibit a ceiling effect on the degree of analgesia that they can produce. Opiate agonist/antagonists and partial agonists can precipitate opioid withdrawal reactions. The respiratory depressant effects of partial agonists are not completely reversed with naloxone.

4.1.2 Opioid categories

The Drug Enforcement Agency (DEA) classifies opioids into schedules as illustrated in Table 8.

The phenanthrenes are the prototypical opioids. The presence of a 6-hydroxyl may be associated with a higher incidence of nausea and hallucinations. For example, morphine and codeine (both with 6-hydroxl groups) are associated with more nausea than are hydromorphone and oxycodone (which do not have 6-hydroxyl groups). Opioids in this group include morphine, codeine, hydromorphone, levorphanol, oxycodone, hydrocodone, oxymorphone, buprenorphine, nalbuphine, and butorphanol.

The lone member of the benzomorphan class is pentazocine. It is an agonist/antagonist with a high incidence of dysphoria.

Phenylpiperidines include fentanyl, alfentanil, sufentanil, and meperidine. Fentanyl has the highest affinity for the mu receptor.

Diphenylheptanes include propoxyphene and methadone.

Tramadol does not fit in the standard opioid classes (Fig. 7).

Opioid antagonists

Naloxone is a pure competitive antagonist at μ, κ, and δ receptors (strongest at μ). It rapidly reverses opioids, but the action is short lived, therefore has the potential for "re-narcotizing."

Table 8. *DEA schedules of controlled drugs*

Schedule	Criteria	Examples
I	No medical use; high addiction potential	Heroin, marijuana, PCP
II	Medical use; high addiction potential	Morphine, oxycodone, methadone, fentanyl, amphetamines
III	Medical use; moderate addiction potential	Hydrocodone, codeine, anabolic steroids
IV	Medical use; low abuse potential	Benzodiazepines, meprobamate, butorphanol, pentazocine, propoxyphene
V	Medical use; low abuse potential	Buprenex, Phenergan with codeine

Naltrexone is used orally in high dose to detoxify opioid addicts. Its primary effect is from its metabolite, 6-β-naltrexol.

Opioid agonist-antagonists

Opioid agonist-antagonists are classified into two types:

Partial agonists at μ receptor, such as buprenorphine, have a high affinity but low efficacy at the μ receptor.

Agonist/partial agonist at κ receptor, such as nalorphine, pentazocine, nalbuphine, and butorphanol, act as κ agonists but are competitive μ antagonists, with a high affinity but no efficacy at the μ receptor. Methylnaltrexone and alvimopan have poor oral absorption and are under investigation for use as oral agents to reverse the decreased GI motility of opioid agonists.

These agonist-antagonists are potent analgesics with ceiling effect and therefore potentially decreased abuse potential. It must be remembered that their antagonist properties may precipitate withdrawal.

4.1.3 Opioid metabolism

Many of the side effects of opioids, as well as their effects, may be related to the opioid metabolites. It is generally assumed that most of the metabolism occurs in the liver. The basal rate of metabolism is determined by genetic makeup, gender, age, as well as environment including diet, disease state, and concurrent use of medications. There is no clear evidence of renal metabolism, though the kidney is an important site of excretion. Most opioids are metabolized by glucuronidation or by the P450 (CYP) system. In humans, 57 cytochrome P-450 genes have been identified (148).

CYP3A4 is the most abundant enzyme in the body at 25% (149). Levels of CYP3A4 may vary as much as 30-fold between individuals (149), leading to large variability in blood levels. CYP1A2, CYP2C8 and CYP2C9 make up about 10% of the enzymes, CYP2D6 and CYP2E1 each around 5%, and CYP2C19 around 1%. CYP2D6 is entirely absent in some populations, for example, 6-10% of Caucasians are 2D6 deficient (150) while other persons have high levels of this enzyme, leading to rapid metabolism of the medicines. Because of genetic polymorphism and variant alleles of the cytochrome P-450 genes, patients may be either rapid or slow metabolizers of opioids. The possibility exists that genotyping will allow identification of these patients, with the ability to titrate their doses appropriately.

4.2 Pharmacology of Specific Opioids

4.2.1 Morphine

Morphine is a strong Schedule II analgesic, indicated for severe acute pain, or moderate to severe chronic pain. The primary site of action is the CNS. The oral form is available in immediate-release and extended-release dosage forms. The parenteral forms of morphine contain sulfites that may cause anaphylactic or life threatening, allergic-type reactions in individuals with sulfa allergies.

Morphine is a phenanthrene derivative and is the prototype μ receptor opioid agonist. The absorption of morphine after oral administration varies from 20% to 30%. Morphine is a relatively long-lasting opioid with analgesic effects lasting 4-5 hours. Its elimination half-life is 2 hours which is actually less than shorter acting opioids such as fentanyl. Morphine is relatively water soluble. This discrepancy is explained by the low lipid solubility of morphine and its slower elimination from the brain compartment in relation to the plasma concentration, which also may be associated with its existence in an ionizable state in the relatively acid brain compartment. The relatively long analgesic ac-

tivity of morphine may be associated with the presence of the active morphine metabolites, which have half-lives of elimination longer than morphine itself. As with other strong opioid analgesics, there is no ceiling to the analgesic effect. However, significant side effects, particularly sedation and confusion, may interfere with achieving optimal analgesia (151).

Approximately 50% to 80% of the dose administered is typically recovered as glucuronide metabolites, mostly morphine-3-glucuronide (M3G) and morphine-6-glucuronide (M6G), whereas approximately 2% to 8% of the dose typically is found in urine as unmetabolized morphine. Morphine is also metabolized to codeine, normorphine-3, 6-diglucuronide, and morphine-3-sulfate. The liver is the major site of metabolism of morphine, even though extrahepatic glucuronidation has been reported. Morphine glucuronides are eliminated from the body by urinary secretion. During long-term morphine administration, circulating concentrations of M3G and M6G markedly exceed those of morphine itself because hepatic metabolism converts approximately 70% of morphine into M3G (60%) and M6G (10%). M6G and normorphine are both opioid agonists; M6G is 3-4 times more potent than morphine when injected subcutaneously, and 45 times more potent after intracerebroventricular injections in mice (152). M3G has a low affinity for the opioid receptor, and may be responsible for the side effects of hyperalgesia, and myoclonus (153-155). Hepatic (156) and renal (157) disease may significantly prolong the effect of morphine. Accumulation of morphine metabolites (especially M6G) becomes significant as creatinine clearance declines below 50 ml/min (158). A steady state for long acting preparations is usually reached in 1-2 days. In adults, long-term oral administration of morphine produces variable plasma ratios of M3G and M6G, with reported mean ratios between 10:1 and 5:1.

4.2.2 Codeine

Codeine, first isolated in 1832, is the prototype of the weak opioid analgesics with weak affinity to μ opioid receptor. Codeine in its pure form is a Schedule II substance, but in combination with other analgesics, it is Schedule III. Its analgesic potency is approximately 50% of the morphine with a half-life of 2.5 to 3 hours.

Codeine is a pro-drug, and has no effect until metabolized by CYP2D6 to morphine (159, 160). Genetic deficiencies and multiple drugs interactions can lead to its ineffectiveness (151).

Codeine is also metabolized by glucuronidation to codeine-6-glucuronide (C6G). Minor metabolic pathways result in other metabolites including nor-codeine and morphine (161). C6G has been shown to be antinociceptive in rats (162). Doses of codeine greater than 65 mg are not well tolerated. Codeine has a half-life of 3 hours, and >80% of the dose is excreted in 24 hours.

4.2.3 Dihydrocodeine

Dihydrocodeine is similar to codeine and also has a pharmacokinetic pattern similar to it. In the commercial form it is available as Synalgos-DC (163). Most of dihydrocodeine is conjugated to inactive dihydrocodeine-6-glucuronide. Less than 10% of dihydrocodeine is metabolized to nordihydrocodeine and to dihydromorphine (DHM). DHM has stronger affinity to μ opiate receptor than morphine itself, and it is also conjugated further to the next active metabolite, DHM-6-glucuronide and inactive DHM-3-glucuronide (164). Dihydrocodeine has a half-life of about 4 hours.

4.2.4 Hydrocodone

Hydrocodone is a mild opioid agonist and is indicated for moderate to moderately severe pain as well as symptomatic relief of nonproductive cough. Hydrocodone is the most commonly used opioid. Hydrocodone in its pure form is a Sched-

Opioid categories	Chemical Structure
Phenanthrenes	Morphine
Benzomorphans	Pentazocine
Phenylpiperidines	Fentanyl
Diphenylheptanes	Methadone

Fig. 7. *Opioid classification*

ule II substance; however it is only available for pain control as an oral, combination product with non-opioid analgesics, such as ibuprofen and acetaminophen. As a combination product, hydrocodone is a Schedule III substance because the amount of hydrocodone is limited to a maximum 15 mg per dosage unit. The maximum recommended daily dose of hydrocodone is 37.5 mg when combined with ibuprofen or 60 mg when combined with acetaminophen (165).

Hydrocodone bioavailability after oral administration is high and its effectiveness is similar to that of morphine with oral administration. The half-life of hydrocodone is 2.5 to 4 hours. Hydrocodone undergoes extensive hepatic conjugation and oxidative degradation to a variety of metabolites excreted mainly in the urine. Two major metabolites of hydrocodone excreted in the urine are dihydrocodone and nordihydrocodone, both conjugated to approximately 65%. Hydrocodone is also metabolized to dihydromorphone (DHM). DHM is produced only in minor amounts and is conjugated further to 85%. Only about 25% of the dose is excreted in 72 hours. Some of the hydrocodone metabolites including DHM, hydromorphone, and dihydrocodone are pharmacologically active on the opioid receptors. They may contribute in various degrees to analgesic activity of hydrocodone or produce unexpected side effects when their excretion is impaired, and may show up on urine drug screens, leading to false accusations of abuse. On the other hand, patients who are CYP2D6 deficient, or patients who are on CYP2D6 inhibitors, may not produce these analgesic metabolites, and may have less than expected analgesia.

4.2.5 Oxycodone

Oxycodone is considered as a moderate to strong opioid agonist and is a Schedule II substance whether alone or in combination with aspirin or acetaminophen. It is used orally for moderate to moderately severe pain and postoperative, post exertional, and post partum pain (166). In recent years, extended-release preparations have been extensively used for moderate-to-severe chronic malignant and nonmalignant pain. The adverse effects of oxycodone are milder than those of morphine, but the addiction potential of oxycodone may be the same or higher than morphine.

Bioavailability of oxycodone is high in oral dosage, with a half-life of 2.5 to 3 hours. It undergoes extensive hepatic conjugation and oxidative degradation to a variety of metabolites excreted mainly in urine. Oxycodone is metabolized by glucuronidation to noroxycodone (which has less than 1% of the analgesia potency of oxycodone), and by 2D6 to oxymorphone. Oxycodone has activity at multiple receptors, but oxymorphone has high affinity for the μ receptor with negligible interaction with κ and δ receptors (167). Oxymorphone is about 10 times more potent than morphine. Oxymorphone is not affected by CY2D6 or CY3A4. Oxycodone is conjugated extensively in the liver, ranging from 15% to 80% of the total dose. However, a minority of the dosage undergoes via hepatic pathways into noroxycodone, oxymorphone, oxycodols and their respective oxides. Less than 10% of unchanged oxycodone is excreted in the urine. Significant individual variation in oxycodone metabolism may account for abnormal responses (168).

4.2.6 Hydromorphone

Hydromorphone is a Schedule II semi-synthetic opioid agonist and a hydrogenated ketone of morphine (169, 170). It has been widely used for acute pain, chronic cancer pain, and to a lesser extent in chronic non-malignant pain. Hydromorphone is structurally very similar to morphine (171). Like morphine, it acts primarily on μ opioid receptors and to a lesser degree on delta receptors (172).

Hydromorphone is significantly more potent than morphine, with estimates of a relative potency of 7:1 up to 11:1 compared to morphine. It is highly water soluble which allows for very concentrated formulations. In patients with renal failure it may be preferred over morphine due to morphine's risk of toxic metabolite accumulation.

Hydromorphone is available in various formats: powder, solution, intermediate release tablet and modified-release tablet. Hydromorphone is extensively metabolized in the liver with approximately 62% of the oral dose being eliminated by the liver on the first pass, partly accounting for oral bioavailability in the range of 1:2 to 1:8 (173). For orally administered immediate release preparations, the onset of action is approximately 30 minutes with a duration of action of 4 hours (173). Hydromorphone can also be administered parenterally by intravenous, intramuscular, and subcutaneous routes.

Hydromorphone is metabolized primarily to hydromorphone-3-glucuronide (H3G), which, similar to the corresponding M3G, is not only devoid of analgesic activity but in animal models also evokes a range of dose-dependent excited behaviors, including allodynia, myoclonus and seizures.

4.2.7 Methadone

Methadone is a synthetic μ opioid receptor agonist Schedule II drug (157). Methadone, in addition to its opioid receptor activity, is an antagonist of N-methyl-D-aspartate (NMDA) receptors. Methadone is a racemic mixture of two enantiomers, R-methadone accounts for most of its opioid effect while L-methadone is the NMDA antagonist. The inherent NMDA antagonistic effects make it potentially useful in severe neuropathic and "opioid-resistant" pain states. The L isomer also inhibits reuptake of serotonin and norepinephrine, which should be recognized when using selective serotonin reuptake inhibitors (SSRIs).

Methadone is metabolized by 3A4 primarily, and 2D6 secondarily (173, 174, 175). CYP1B2 is possibly involved, and a newly proposed enzyme CYP2B6 may be emerging as an important enzyme intermediary metabolic transformation. The potential differences in enzymatic metabolic conversion of methadone may explain the inconsistency of observed half-life.

Methadone has several advantages in the treatment of chronic pain. It has excellent oral bioavailability (up to 100% absorbed), though it is highly variable (from 40% to 100%). It can be crushed or dissolved to deliver down a nasogastric (NG) tube. It can be used in patients with a true morphine allergy. Methadone is metabolized in the liver and intestines, and is excreted almost exclusively in feces, an advantage in patients with renal insufficiency or failure. It may also cause less constipation than morphine, and it is very inexpensive (176).

The plasma levels decline following a biexponential model – 2 to 3 hours of initial phase followed by a 15 to 60 hours of terminal phase. This may partly explain its difference in analgesic action and accumulation of the drug with repeated dosing. Most would agree that the analgesic capacity of methadone is significantly shorter than its known half-life. Eight hours of analgesic relief may be overshad-

owed by the up to 120-hour half-life of the drug. Methadone has the potential to initiate Torsade de Points, a potentially fatal arrhythmia caused by a lengthening of the QT interval.

Plasma levels of methadone are increased by concomitant administration of cimetidine, erythromycin, ketoconazole, and fluvoxamine. Conversely, plasma levels are decreased by concomitant administration of barbiturates, phenytoin, carbamazepine, isoniazid, rifampin, ritonavir, nevirapine, and possibly efavirenz.

Methadone may be unique in its lack of profound euphoria, and patient self-directed redosing and long half-life may result in accumulation, with ultimate adverse outcomes including respiratory depression and death. Even when prescribed in low doses, and used appropriately by individuals experienced with opioids, the long half-life of methadone may be underestimated while dosing is titrated to analgesic effect. Furthermore, the list of drug interactions with methadone is extensive, and further alteration in metabolism may occur innocently and unexpectedly, without the prescribing physician's awareness.

4.2.8 Fentanyl

Fentanyl is a strong opioid agonist, a Schedule II substance, available in parenteral, transdermal, and transbuccal preparations (157). Fentanyl is the oldest synthetic piperidine opioid agonist, interacting primarily with μ receptors. It is approximately 80 times more potent than morphine and is highly lipophilic and binds strongly to plasma proteins.

Fentanyl undergoes extensive metabolism in the liver. When administered as a lozenge for oral transmucosal absorption, a portion is swallowed and is subject to first-pass metabolism in the liver and possibly the small intestine. It is metabolized to hydroxyfentanyl and norfentanyl.

Fentanyl is metabolized by 3A4, but to inactive and nontoxic metabolites. The transdermal formulation has a lag time of 6-12 hours to onset of action after application, and typically reaches steady state in 3-6 days. When a patch is removed, a subcutaneous reservoir remains, and drug clearance may take up to 24 hours.

4.2.9 Meperidine

Meperidine is a Schedule II, relatively weak opioid μ agonist with only approximately 10% of the effectiveness of morphine with significant anticholinergic and local anesthetic properties, and with an oral-to-parental ratio of 4:1. The half-life of meperidine is approximately 3 hours. It is metabolized in the liver to normeperidine, which has a half-life of 15-30 hours as well as significant neurotoxic properties. Meperidine must not be given to patients being treated with monoamine oxidase inhibitors (MAOI); combination with MAOIs may produce severe respiratory depression, hyperpyrexia, CNS excitation, delirium, and seizures.

Meperidine is metabolized by glucuronidation to normeperidine, which causes CNS stimulation and seizures, especially with high doses or renal insufficiency. Normeperidine has a terminal half life of 8-12 hours so significant amounts can accumulate in only 2 days. Adverse effects of normeperidine are not reversible by naloxone.

4.2.10 Pentazocine

Pentazocine is a semisynthetic derivative of the benzomorphans, a Schedule IV substance. It interacts with μ receptors and κ receptors. It is considered a mixed opioid agonist-antagonist. It is manufactured as a racemic mixture (L:R 50:50), but only the L-isomer possesses analgesic activity. It is well absorbed after oral administration. The half-life of pentazocine is about 4 hours. It is metabolized almost exclusively in the liver to inactive glucuronides and oxidation of the terminal methyl groups.

4.2.11 Propoxyphene

Propoxyphene is a mild, opioid agonist used in mild to moderate pain and is a Schedule IV substance. Propoxyphene has CNS effects such as dizziness, sedation, weakness and falls, mild visual disturbances, agitation, paradoxical excitement, and insomnia. These effects become more common and can result in drug-related deaths when propoxyphene is used in combination with other drugs that can cause drowsiness (166,177). The GAO, after two studies conducted in 1991 and 1995, recommended that propoxyphene not be used in elderly patients because of the existence of other analgesic medications that are more effective and safer (177, 178). Propoxyphene is a synthetic analgesic that is structurally related to methadone and has an opioid dose equipotency similar to codeine. The analgesic activity is confined to its d-stereoisomer (dextropropoxyphene) with a half-life of 6 to 12 hours, with duration of effective analgesia of 3 to 5 hours. It is metabolized in the liver to norpropoxyphene, which has a long half-life of 30 to 60 hours and is considered to have cardiac toxicity. Further, propoxyphene itself can produce seizures (naloxone-reversible) after overdose. In addition to being a μ receptor agonist, propoxyphene is a weak and noncompetitive N-methyl-D-aspartate (NMDA) receptor antagonist.

4.2.12 Tramadol

Tramadol is a synthetic opioid that inhibits norepinephrine and serotonin reuptake and produces some central opioid receptor activity (179). The M1 derivative (O-demethyl tramadol) produced by CYP2D6, has a higher affinity for the μ receptor than the parent compound. Tramadol is a racemic mixture of two enantiomers – one form is a selective μ agonist and inhibits serotonin reuptake, while the other mainly inhibits norepinephrine. Maximum dose is 400 mg/day. Toxic doses cause CNS excitation and seizures.

Tramadol is a non-scheduled drug according to federal standards. State regulations may vary. Tramadol is absorbed rapidly and extensively after oral doses, and is equal to the analgesic potency of codeine.

4.3 Adverse Effects

The majority of the adverse effects of opioids reflect the effects of opioids at multiple organ systems (180).

- Central nervous system
  - A sense of emotional well being and euphoria
  - Drowsiness, sedation, or hallucinations
  - Potential for diminished psychomotor performance
  - Dysphoria, agitation, and seizures
- Respiratory system
  - Respiratory depression is the major adverse effect and may result from toxicity.
  - Diminution of pain or pain relief by other modalities may exacerbate respiratory depression (181).
- Ocular system
  - Miosis stimulation occurs through the parasympathetic ganglion.
- Gastrointestinal system
  - Constipation, nausea and vomiting
  - Delayed gastric emptying
- Genitourinary
  - Urinary retention
  - Sexual dysfunction
- Cardiovascular
  - Reduction in systemic vascular

resistance
- Decreased blood pressure but potentially increased cardiac output
- Bradycardia due to vagal stimulation

- Musculoskeletal system
  - Muscle rigidity and myoclonus (182)
- Immune system
  - Itching is common due to a direct histamine release (especially by morphine)
  - Not an allergic reaction (183, 184)
- Pregnancy
  - All opioids cross the placenta
  - Neonatal depression can occur if opioids are used during labor
  - No teratogenic effects have been observed
- Tolerance
  - Decreased duration of analgesia and then decreased effectiveness.
- Physical dependence
  - Withdrawal symptoms include runny nose, shivering, "goosflesh," diarrhea, and mydriasis

4.4 Drug Interactions

A drug interaction occurs when the amount or the action of a drug are altered by the administration of another drug or multiple drugs (185). Multiple hepatic drug interactions may influence opioid drug levels (118, 188), as illustrated in Table 9.

- There have been isolated reports of interactions between opioid and H2 blockers (cimetidine and ranitidine) causing breathing difficulties, confusion, and muscle twitching.
- A patient taking Tamoxifen (a CY2D6 substrate) was noted to get poor relief with oxycodone (which is metabolized by CY2D6) but excellent relief with morphine (168).

Methadone has multiple drug interactions. Phenytoin, carbamazepine, rifampin, erythromycin, barbiturates, and several anti-retrovirals induce methadone metabolism, resulting in decreased blood levels and the potential for withdrawal. The azole antifungals, the SSRIs, and tricyclic antidepressants may increase methadone levels (189). Methadone may also increase TCA levels. Overmedication occurring within a few days is usually due to P450 (CYP) inhibition, while withdrawal reactions taking a week or more are usually due to CYP induction (190). Methadone also has the potential to cause cardiac arrhythmias, specifically prolonged QTc interval and/or torsade de pointes under certain circumstances. Combining methadone with a CYP3A4 inhibitor such as ciprofloxin (191), and even grapefruit, can increase that risk (192). It is recommended that a switch to methadone from another opioid be accompanied by a large (50% to 90%) decrease in the calculated equipotent dose (193).

4.5 Drug Conversions

While there have been multiple opioid conversion charts developed, none are reliable and none take into consideration the vast individual differences in effect and metabolism between patients and within medications. Brand name and generic medications may have significant differences in bioavailability, and metabolism of medications may be influenced by genetic polymorphism and drug interactions. It is therefore important to recognize that "equipotent" doses of medications may have very different degrees of analgesia and side effects. In general, to switch between medications, the clinician must calculate a rough equivalent 24 hour dose, divide by the dosing schedule, and then "under-dose," with subsequent titration to effect.

Most authors agree that oral morphine intravenous (IV) morphine: intrathecal morphine equivalency is 30:10:1. Hydromorphone is approximately five times more potent than morphine. Ten mg to 20 mg of IV morphine is roughly equivalent to 25 mcg of transdermal fentanyl. Oral oxycodone is about two-thirds as potent as morphine. Although methadone has been described as equipotent to morphine, it is now clearer that dosing methadone on a milligram-for-milligram basis will lead to life-threatening overdose. For doses of morphine under 100 mg, a ratio of 3:1 may be appropriate, while for higher doses of morphine a ratio of 20 mg of morphine for each mg of methadone may be appropriate (194). It cannot be too strongly emphasized that the dosing of methadone can be potentially lethal and must be done with knowledge and caution.

4.6 Opioid Therapy and Side Effects

4.6.1 Long-term opioid therapy

While advocacy for appropriate opioid usage in chronic pain continues, it is well known that prolonged use of opioids may result in adverse consequences, including tolerance, hyperalgesia, hormonal effects, and immunosuppression (195). However, the clinical relevance of these problems is only known for opioid tolerance. It is postulated that prolonged use of high doses of opioids is likely to be more toxic than short-term use of low doses, and hormonal effects are most likely to occur in patients with chronic pain who receive high dose opioid therapy (89). The essential aim of a multitude of available guidelines is to protect patients from the adverse effects of opioid therapy in addition to providing access. Paradoxically, opioid treatment may be offered in an attempt to reduce pain and improve function, and thereby reduce the burden

Table 9. *Drug interactions of opioids*

Tricyclic antidepressants	Inhibit morphine glucuronidation leading to ↑ blood levels – Nortriptyline inhibits non-competitively – Amitriptyline and clomipramine inhibit competitively
Methadone and morphine	↓ metabolism of desipramine, leading to toxicity
Quinine	↓ conversion of codeine to morphine leading to ↓ analgesia
Metoclopramide	Earlier peak plasma levels with controlled-released opioids
Meperidine	MAO inhibitors trigger hyperpyrexia
Propoxyphene	↑ carbamazepine, doxepin, metoprolol, propranolol levels ↓ excretion of benzodiazepines, leading to accumulation and overdose
Erythromycin	↑ opioid effects
Rifampin	↓ opioid effects
CY2D6 inhibitors	↑ tramadol levels ↓ analgesia from hydrocodone/codeine
CY2D6 substrates	↑ tramadol levels because of competition for metabolism

of care, but the treatment may actually increase the burden of care, because the management of opioid therapy in patients with complex problems is time consuming and difficult (89).

The adverse effects of long-term opioid therapy for the treatment of chronic pain may be avoided or reduced by multiple means. These include limiting the opioid dose, changing the drug formulation, opioid rotation, and understanding that despite all the changes and strategies, escalation of the opioid dose may fail (89).

4.6.2 Opioid Induced Immunologic Effects

Opioids are known to effect immune function in many ways that are measurable (196-212). It is accepted that acute administration of opioid agonists is immunosuppressive (197-199). The animal studies have shown that the prototypical opioid morphine suppresses natural killer cell activity (NKCA), inflammatory cytokine production, and mitogen-induced lymphocyte proliferation (196, 200, 201). The human studies provided similar results with morphine and fentanyl (205, 206). Repeated and chronic opioid ingestion in the absence of pain appears to result in significant consequences including high infectious disease prevalence (196, 207). However, in the presence of acute pain, there is evidence that opioid administration in analgesic doses is protective, since pain, in and of itself, has been shown to be immunosuppressive (196, 199, 208, 209). However, much less is known regarding the immune and disease implications related to chronic opioid treatments for chronic pain states. Despite exhibiting normal circulating levels of immunoglobulins throughout, pain patients exhibited reduced in vitro production of immunoglobulins, both before therapy initiation and throughout (210).

4.6.3 Opioid Induced Hormonal Changes

Opioids influence the hypothalamic-pituitary-adrenal axis and hypothalamic-pituitary-gonadal axis, along with others (213-226). Morphine has been reported to cause a strong, progressive decline in the plasma cortisol levels in laboratory animals and humans (213-215). The major effects of opioids include an increase in prolactin and a decrease in luteinizing hormone, follicle-stimulating hormone, testosterone, and estrogen by modulation of hormonal release involving hypothalamic-pituitary-gonadal access (216, 223, 224). While there are no studies to address multiple hormonal issues related to chronic pain and opioid therapy, testosterone depletion has been demonstrated in patients on methadone maintenance therapy (217-219, 223-225). The effect of testosterone depletion may result in hypogonadism, decreased libido, aggression, and drive; amenorrhea or irregular menses; and galacturia (220, 221). In fact, clinically relevant testosterone depletion has been reported to develop in the majority of men receiving intrathecal opioid therapy for chronic pain, and they benefited from testosterone-replacement therapy (221, 222), with an increase in analgesia as well as a decrease in testosterone deficiency symptoms.

4.6.4 Opioid Induced Hyperalgesia

Hyperalgesia or abnormal pain sensitivity manifests as increased pain from noxious stimuli and as pain from previously non-noxious stimuli. Long-term use of opioids may be associated with the development of hyperalgesia (227-230). Experimental and clinical studies describe that cellular mechanisms of neuropathic pain may be similar to opioid-induced hyperalgesia (229-232). In an experimental setting, NMDA-receptor-mediated changes that cause abnormal pain sensitivity have been shown to occur in animals in the spinal cord dorsal horn cells of animals after repeated exposure to opioids (233). Similarly, these changes have been observed in the spinal cord in animal models of neuropathic pain. Consequently, interactions between neural mechanisms of opioid tolerance and neuropathic pain involving spinal and supraspinal neural circuits may have important clinical implications (227, 234).

Repeated administration of opioids not only results in the development of tolerance but also hyperalgesia. In fact, opioid-induced abnormal pain sensitivity has been observed in patients treated for both pain and addiction (23, 235-239). It also has been postulated that there may be correlation between tolerance which is a desensitization process, and hyperalgesia which is a pro-nociceptive process or sensitization. In prolonged opioid therapy, desensitization and sensitization together may contribute to tolerance or an afferent decrease in analgesia, regardless of the progression of the pain (238). Ballantyne and Mao (89) stated that the need for dose escalation during opioid therapy – that is, the development of "afferent" opioid tolerance – may result from pharmacologic opioid tolerance, opioid-induced abnormal pain sensitivity, or disease progression. The potential use of NMDA antagonists in the treatment of neuropathic pain, opioid tolerance, and opioid-induced hyperalgesia is the subject of multiple investigations.

4.6.5 Psychomotor Performance In Opioid Therapy

The negative effects of opioids on psychomotor performance in the opioid-naïve patient are well known (239-242). In addition, some believe that once opioids are added to the management of pain, a patient's ability to operate heavy equipment is diminished and they should not be allowed to drive an automobile (243). However this view is contradicted by others who believe that patients on stable doses of opioid medications should be allowed to drive vehicles (244). The only direct evidence provided in a subset of patients with chronic pain on a stable opioid analgesic regimen (240) shows that these patients are capable of safely operating an automobile during daytime, in normal weather conditions. On virtually every dependent measure tested, this study showed no significant difference among patients with chronic pain without opioids, healthy patients or volunteers, and chronic pain patients on opioids. However, in another study evaluating the effects of immediate-release morphine and cognitive functioning in patients receiving chronic opioid therapy (245), the study suggested that immediate release morphine, when taken on top of sustained release opioid, produced transient anterograde and retrograde memory impairments and a decrement in two-target tracking, leading the authors to conclude that these impairments may have impact.

4.6.6 Breakthrough Pain Management

Breakthrough pain and its management is a controversial issue. A prospective study (246) of breakthrough pain and its clinical applications defined breakthrough pain as a transitory flare of pain beyond moderate intensity in the setting of chronic pain stabilized by opioid therapy. Evaluation of opioid therapy in 63 cancer pain patients showed that 64% of them experienced breakthrough pain. However, except for the application of cancer pain patient data to non-

cancer pain patients, there have not been systematic evaluations. Indications for breakthrough pain may be abused for additional opioid therapy in chronic non-cancer pain.

5.0 Terminology of Abuse and Addiction

5.1 Introduction

The terminology related to abuse and addiction of opioids and other controlled substances is considered confusing and reflects a lack of understanding of the multiple issues related to abuse and addiction. Savage et al (247) described the scientific basis of addiction-related terms. They provided three fundamental concepts related to addiction in order for it to reflect current scientific and clinical understanding: 1) criteria determination of addiction rests with the user even though some drugs produce pleasurable reward; 2) addiction is a multidimensional disease with neurobiological and psychosocial dimensions; and 3) addiction is a phenomenon distinct from physical dependence and tolerance.

5.2 History

Historically terminology has not clearly reflected the above-mentioned essential elements and despite significant growth in understanding of the scientific basis of addiction, definitions and diagnostic criteria persist that are based on obsolete conceptualizations of addiction. The terms have been defined by the World Health Organization (WHO), the Diagnostic and Statistical Manual of Mental Disorders, fourth edition (DSM-IV) and United States federal and state policies, as well as other organizations by means of consensus statements.

In 1952, in connection with its role in the international control of drugs, the WHO used two terms: "addiction" and "habituation." Addiction was viewed primarily as the direct effect of certain drugs, and secondly as due to the psychologic make-up of the drug taker. In contrast, habituation was viewed as occurring in response to other drugs which never produce compulsive craving, yet their pharmacologic action is found desirable by some individuals to the point that they readily form a habit of administration (248). The distinction between the two terms lacked clarity and confused most professionals. In 1957, a committee of experts on the addiction-producing drugs convened by the WHO introduced the terms psychological dependence and physical dependence (248). Addiction was characterized by the presence of both physical and psychological dependence and was viewed as primarily drug induced. In 1964, WHO stopped using the terms addiction and habituation altogether and introduced the term drug dependence in their place, noting that dependence is either psychological or physiologic or both, and is a common feature of both conditions (249). In 1969, the WHO re-conceptualized the definition of drug dependence to include significant behavioral criteria and to explicitly acknowledge that drug dependence is due to both host and drug factors (250). In 1993, the WHO expert committee on drug dependence noted the potential for confusion between the terms physical dependence and drug dependence and substituted the term withdrawal syndrome for physical dependence (251). In 1998, the expert committee replaced the term drug dependence with dependence syndrome, but reaffirmed its 1993 definition without revisions (252). Consequently, the 1998 term "dependence syndrome" and the 1993 term "withdrawal syndrome" represent the current WHO nomenclature (252).

The Controlled Substance Act defined addiction as a term meaning any individual who habitually uses any narcotic drug so as to endanger the public morals, health, safety, or welfare or who is so far addicted to the use of narcotic drugs as to have lost the power of self-control with reference to his or her addiction (70).

DSM-IV defines substance abuse and dependence. Substance abuse is a maladaptive pattern of substance use leading to significant impairment or distress in the last 12 months with one (or more) events such as failure to fulfill major role obligations, using inappropriate substances, participating in hazardous situations, being involved in recurrent substance related legal problems and/or continuing use in the face of adverse consequences. In contrast, DSM-IV defines substance dependence as a maladaptive pattern of substance use leading to significant impairment or distress in the last 12 months, meeting the criteria for substance abuse plus three or more of the following seven criteria during the same 12 month period: tolerance, withdrawal, inability to control use, unsuccessful attempts to decrease or discontinue use, a great deal of time lost in obtaining the substance, using the substance, or recovering from its effects, important activities given up because of use, continued use despite physical or psychological problems caused by use, and continued use of a substance.

Considering that there is significant confusion among all the definitions, several organizations have also defined and clarified various terms. These definitions are related to tolerance, physical dependence, and addiction.

Tolerance is the need for an increased dosage of a drug to produce the same level of analgesia that previously existed. Tolerance is also suspected when a reduced physiologic effect is observed with constant dosing. Analgesic tolerance is not always evident during opioid treatment, and is not to be confused with addiction, which occurs as a dysfunctional craving of a drug action by physiologic action and psychologically driven factors.

Physical dependence is a state of adaptation manifested by a drug class specific withdrawal syndrome that can be produced by drug cessation, rapid dose reduction, decreasing blood level of the drug, and/or administration of an antagonist. Physical dependence is a normal adaptation to the drug, reinforced by continued use. Physical dependence is most commonly associated with withdrawal symptoms when the substance is abruptly discontinued.

Addiction by contrast, is compulsive use of a drug despite physical harm, and the terms tolerance and addiction are not interchangeable. The terminology may share similar characteristics, as many addicts do become tolerant of their chosen drug, which can be expected with regular use. Addiction is a dysfunctional use behavior that includes one or more of the following: impaired control over drug use, compulsive use, continued use despite harm and craving; however, tolerance is a physiologic alteration of metabolism.

In a chronic pain state, a patient may be exposed to a controlled substance for a prolonged period of time, developing tolerance and physical dependence. Addiction may occur, but is an unlikely event. Dependence does not foreshadow harm, or intent at self-destructive behavior. It is therefore, incumbent upon the pain management physician to determine that these definitions and their physiolog-

ic undertones are well understood, and that the overlap of these definitions does not necessarily define a controlled substance risk, or an inappropriate patient. In other words, tolerance and dependence share many common physiologic characteristics, and addiction may be associated with, but not be defined by, either or both. Physical dependence, addiction, and tolerance are physiologic, social, and psychological considerations with prolonged substance management.

6.0 Clinical Effectiveness

6.1 Introduction

Controversy over the prescription of opioids for chronic non-malignant pain continues despite the growing acceptance of this practice and claims that pain is undertreated. The use of opioids has been endorsed by multiple societies and advocacy organizations as appropriate treatment for refractory chronic non-cancer pain in the general population as well as in older patients, when used judiciously and according to guidelines similar to those used for cancer patients. While all agree that opioids are indicated in cancer pain, questions continue to arise about opioid usage in non-cancer pain on a long term basis.

6.2 Systematic Reviews

Extensive review of the literature was presented by two systematic reviews and two narrative and analytic reviews.

A systematic review by Chou et al (90) evaluated the comparative efficacy and safety of long-acting oral opioids for the treatment of chronic non-cancer pain. This systematic review had a broad scope and key questions including evaluation of the population, drugs, outcomes, and study types. The methodology included an extensive search of literature published between 1980 and 2001, study selection, data abstraction, quality assessment, and data synthesis. Results gave an overview of included trials, answers to key question outcomes, and a summary of evidence. They identified 16 randomized trials with 1,427 enrolled patients that evaluated long-acting opioids in a chronic non-cancer pain population. They included controlled clinical trials to evaluate efficacy, and they also included observational trials to evaluate adverse event rates. In this systematic review, the results showed that only two of the 16 trials compared one long-acting opioid to another (253,254). Seven trials (255-261) compared a long-acting opioid to a short-acting opioid, and seven trials (262-268) compared a long-acting opioid to a non-opioid or placebo. The trials ranged in size from 12 patients to 295 patients, with an average enrollment of 79 patients. The trials were focused on multiple pain problems: five on back pain; five on osteoarthritis; two on neuropathic pain; one on phantom limb pain; and three on heterogenous chronic non-cancer pain. All of the trials were of relatively short duration, ranging from 5 days to 16 weeks. In head-to-head comparisons, the results showed poor evidence that one or more long-acting opioids were superior to other long-acting opioids in reducing pain and improving functional outcomes when used for treatment of adults with chronic non-cancer pain. The evidence was poor in comparing long-acting opioids to other types of drugs or to placebo in suggesting that one long-acting opioid was more effective than another. Evidence was also poor with regards to long-acting opioids being superior to short-acting opioids in reducing pain and improving functional outcomes when used for treatment in adults with chronic non-cancer pain. Finally, the evidence was also poor as to the effectiveness or fewer adverse effects of one long-acting opioid versus another in evaluated subpopulations, or patients with chronic non-cancer pain. The authors were concerned over a lack of high-quality evidence comparing long-acting opioids to one another, and to short-acting opioids, in patients with chronic non-cancer pain. They felt that data was inadequate to determine whether long-acting opioid preparations, either compared to each other or to short-acting opioids, have different efficacy and safety profiles.

The second systematic review by Kalso et al (91) included in their methodology section the search criteria, inclusion criteria and reporting, data extraction, and analysis. They provided results of included studies, quality and validity, description of the patient population, oral opioid dosing, and open label follow-up studies. They included 18 randomized, double-blind, placebo-controlled trials which met inclusion criteria. In this systematic review, 11 studies (254, 256, 262, 264-266, 268-272) compared oral opioids with placebo, over periods ranging from 4 days to 8 weeks, with open follow-ups of up to 2 years. They included seven studies (254, 256, 262, 264-266, 268) in the review, which were also included by Chou et al (90). Patients in most studies had previously used opioids. Six of the studies dealt with neuropathic pain, four with musculoskeletal pain, and one with mixed pain. Of 1,025 randomized patients, 674 completed the studies. Adverse effects and lack of efficacy were the most frequent reasons for discontinuation during both opioid and placebo treatments. They concluded that opioids alleviated nociceptive and neuropathic pain, but trials reported large individual variations. The mean pain relief with opioid was about 30%. The lowest maximum doses, morphine 30 mg and oxycodone 20 mg daily were used in musculoskeletal pain and were not effective. About 80% of patients experienced at least one adverse event, with constipation (41%), nausea (32%), and somnolence (29%) being most common. Only 44% of the 388 patients on open label treatments were still on opioids between 7 and 24 months after therapy. The conclusions were that the short-term efficacy of opioids was good in both neuropathic and musculoskeletal pain conditions. However, only a minority of patients in these studies went on to long-term management with opioids.

A narrative review by Ballantyne and Mao (89) also reviewed clinical studies. They concluded that a cautious approach must be used in dose escalation and further recommended discontinuation of opioid if treatment goals are not met. They also recommended that it is imperative physicians make every effort to control indiscriminate prescribing even when they are under pressure by patients to increase the opioid dose. They reviewed 16 randomized trials (254, 259, 262, 263, 266-268, 270, 271, 273-279). Of these, 15 showed significant analgesic efficacy for periods of one week to several months. However, beneficial effects on functioning were observed less consistently (253, 254, 259, 260, 262, 266, 267). Ballantyne and Mao (89) included seven studies (254, 256, 259, 262, 263, 267, 268) from Chou et al (90). They also reviewed two studies (270, 271) from Kalso et al (91).

Bloodworth (88) reviewed and analyzed multiple issues in opioid management. She performed a review of published trials and identified 26 citations that evaluated the effects of short- or long-term opioids in adults experiencing

chronic, non-malignant pain (253, 254, 260, 262, 263, 266, 267, 270, 275, 277, 279-293). She included not only randomized trials but also observational reports (286-289). She included eight studies from Chou et al (90), four studies from Kalso et al (91), and nine studies from Ballantyne and Mao (89). The average change in pain intensity from baseline was 27.8% for patients receiving opioids versus 6.8% for patients receiving placebo. Over one-third of patients receiving a trial of opioids rejected the trial because of adverse effects. Bloodworth also reported that, based on the results, long-term use of opioid therapy is not associated with fine motor or cognitive impairment in the majority of patients with chronic back pain.

The four reviews described above, two systematic and two narrative, evaluated a total of 32 controlled studies (Table 10). All the reviews provided only limited strength of evidence with regards to the clinical effectiveness of opioids on a long-term basis.

There was also one systematic literature review of reasons for administration, prescription patterns, effectiveness, and side effects of oral methadone for chronic non-cancer pain (290). The authors of this study found a total of 21 papers, one of which was a small randomized trial (291), 13 were case reports, and seven were case series involving 545 patients under treatment for multiple non-cancer pain conditions. Methadone was administered primarily when previous opioid treatment was ineffective or produced intolerable side effects. Starting doses ranged from 0.2 mg to 80 mg per day and maximum doses ranged from 20 mg to 930 mg per day. Meaningful outcomes in pain were reported in 59% of the patients in the uncontrolled studies. The single randomized trial (291) demonstrated a statistically significant improvement in neuropathic pain with methadone (20 mg per day) as compared to placebo. Side effects were considered to be minor. However, the authors cautioned that the figure of 59% effectiveness of methadone should be interpreted very cautiously, as it seems overrated due to the poor quality of the uncontrolled studies and their tendency to report positive results.

6.3 Other Controlled Trials

Since the publication of the above reviews, our search yielded 10 additional references as shown in Table 10 (292-301). Of the 10 additional trials found since the publication of the above systematic reviews, five studies evaluated tramadol, two evaluated oxycodone, one evaluated transdermal buprenorphine, one compared transdermal fentanyl to long-acting morphine, and one study evaluated extended-release oxymorphone. Of these, four studies included patients with chronic low back pain, two studies included patients with chronic non-specific pain and four studies included patients with osteoarthritis. None of the studies lasted more than 12 weeks, and therefore have limited applicability to chronic pain patients.

6.4 Influence of Psychopathology on Opioid Effectiveness

Psychopathology in pain patients is very common, with major depression and anxiety seen in as high as 80% of the patients, a factor that may have a negative affect on opioid analgesia in patients with chronic pain (116, 302-315). Depression, anxiety, and neuroticism are disorders of negative affect, which often co-occur in some combination in patients with chronic pain (300). Consequently, disorders of negative affect have been shown to correlate with increased pain intensity and poorer function, regardless of the treatment modality. It was shown that psychopathology predicts poor opioid analgesia in patients with chronic low back pain (302).

6.5 Summary of Evidence

As listed in Table 10, there were 43 studies included in the evaluation. As described in the systematic reviews, the quality of the studies was generally low with regards to chronic pain. Consequently, despite multiple randomized double-blind trials, the evidence was considered as limited due to lack of long-term studies, either comparative or placebo controlled.

In an editorial titled *Potent opioids for chronic musculoskeletal pain: flying blind?*, Von Korff and Deyo (92) discussed various issues related to opioid prescriptions. They concluded that the studies were inadequate in evaluating effectiveness and risks of opioids in chronic non-cancer pain, prescription opioid abuse is increasing, caution must be applied in utilizing consensus recommendations as they are not practical in the real world, and there should be no short cuts around rigorous effectiveness research. Breivik (93) discussed indications and controversies of the use of opioids in treating chronic non-cancer pain. Breivik reported that in some well selected patients with long-lasting or recurrent pain that is severe enough to markedly reduce their quality of life, and for whom no other more effective and less risky therapies are available, opioid analgesics may reduce the intensity of pain, increase functioning, and improved quality of life for prolonged periods.

7.0 Adherence Monitoring

7.1 Introduction

Important issues in opioid therapy for the treatment of chronic pain revolve around the appropriate use of prescription opioids. Consequently, adherence monitoring is crucial to avoid abuse of the drugs and at the same time to encourage appropriate use. Adherence monitoring is achieved by screening tests, urine drug testing, and periodic monitoring.

Confusion surrounding a specific operational definition of opioid misuse among chronic pain patients has complicated the process of effectively assessing and predicting its occurrence (236,316-318).

7.2 Screening for Opioid Abuse

Even though several investigators have described multiple screening instruments in detecting opioid abuse or misuse in chronic pain patients, there is no widely used screening instrument in current practice (319-325). Chabal et al (81) developed a prescription abuse "checklist" consisting of five criteria as listed in Table 11. Compton et al (319) identified three items which were particularly useful in identifying misuses of opioids (Table 11). Passik et al (320) evaluated a questionnaire among a small group of cancer and HIV patients, evaluating medication use, present and past drug use, patients beliefs about addiction risk, and aberrant drug-taking attitudes and behaviors. Atluri and Sudarshan (324) developed a screening tool to detect the risk of inappropriate prescription opioid use in patients with chronic pain, with identification of six clinical criteria as shown in Table 11. Manchikanti et al (322) evaluated Atluri and Sudarshan's (324) assessment tool with identification of three particularly useful factors (Table 11, p 22). Adams et al (316) developed a pain medication questionnaire based on a 26-item in-

Table 10. *Analysis of controlled trials of opioids*

Authors	Chou et al (90)	Kalso et al (91)	Ballantyne and Mao (89)	Bloodworth (88)	Drug(s) Tested	Condition Evaluated
Caldwell et al (254)	Yes	Yes	Yes	Yes	Morphine vs placebo	Osteoarthritis
Caldwell et al (256)	Yes	Yes	Yes	No	Oxycodone-CR vs Oxy with acetaminophen	Osteoarthritis
Harke et al (264)	Yes	Yes	No	No	Morphine-CR vs carbamazepine	Neuropathic pain
Huse et al (265)	Yes	Yes	No	No	Morphine	Phantom-limb pain
Moulin et al (266)	Yes	Yes	Yes	Yes	Morphine	Chronic pain
Roth et al (262)	Yes	Yes	Yes	Yes	Oxycodone-CR vs placebo	Osteoarthritis
Allan et al (253)	Yes	No	No	Yes	Fentanyl, morphine	Chronic pain
Hale et al (255)	Yes	No	No	No	Codeine-CR vs Codeine with acetaminophen	Chronic low back pain
Gostik et al (257)	Yes	No	No	No	Dihydrocodeine-CR vs IR	Osteoarthritis & chronic back pain
Jamison et al (259)	Yes	No	Yes	Yes	Morphine, oxycodone	Chronic low back pain
Lloyd et al (260)	Yes	No	No	Yes	Dihydrocodeine-CR vs propoxyphene	Osteoarthritis
Salzman et al (261)	Yes	No	No	No	Oxycodone-CR vs IR	Back pain
Arkinstall et al (263)	Yes	No	Yes	Yes	Codeine-CR vs placebo	Chronic pain
Peloso et al (267)	Yes	No	Yes	Yes	Codeine-CR	Osteoarthritis
Watson and Babul (268)	Yes	Yes	Yes	No	Oxycodone	Neuropathic pain
Moran (276)	Yes	Yes	Yes	No	Morphine	Rheumatoid arthritis
Gimbel et al (269)	No	Yes	No	No	Oxycodone	Diabetic neuropathy
Maier et al (270)	No	Yes	Yes	Yes	Morphine	Chronic pain
Raja et al (271)	No	Yes	Yes	No	Opioids vs anti-depressants	Post-herpetic neuralgia
Watson et al (272)	No	Yes	No	No	Oxycodone	Diabetic neuropathy
Haythornthwaite et al (273)	No	No	Yes	No	Oxycodone, propoxyphene, codeine, or hydrocodone	Chronic pain
Rowbotham et al (274)	No	No	Yes	No	Levorphanol	Neuropathic pain
Kjaersgaard-Andersen et al (275)	No	No	Yes	Yes	Codeine + paracetamol vs paracetamol	Osteoarthritis
Sheather-Reid and Cohen (277)	No	No	Yes	Yes	Codeine vs ibuprofen	Neck pain, fibromyalgia
Schofferman (278)	No	No	Yes	No	Methadone, levorphanol, morphine	Low back pain
de Craen et al (279)	No	No	No	Yes	Tramadol	Chronic pain
Messick (280)	No	No	No	Yes	Propoxyphene vs APAP	Musculoskeletal pain
Muller et al (281)	No	No	No	Yes	Codeine + paracetamol vs tramadol	Chroric back pain
Mullican and Lacy (282)	No	No	No	Yes	Codeine + APAP vs tramadol	Chroric back pain
Palangio et al (283)	No	No	No	Yet	Hydrocodone vs codeine	Musculoskeletal pain
Salzman and Brobyn (284)	No	No	No	Yes	Suprofen vs propoxyphene	Osteoarthritis
Wilder-Smith et al (285)	No	No	No	Yes	Tramadol SR vs dihydrocodeine SR	Osteoarthritis
Morley et al (291)	No	No	No	No	Methadone	Neuropathic pain
Malonne et al (292)	No	No	No	No	Tramadol SR	Osteoarthritis
Babul et al (293)	No	No	No	No	Tramadol SR	Osteoarthritis
Ruoff et al (294)	No	No	No	No	Tramadol + acetaminophen	Chronic low back pain
Schnitzer et al (295)	No	No	No	No	Tramadol	Chronic low back pain
Sttl et al (296)	No	No	No	No	Transdermal buprenorphine	Chronic pain
Gammaitoni et al (297)	No	No	No	No	Oxycodone + acetaminophen	Chronic pain
Peloso et al (298)	No	No	No	No	Tramadol + acetaminophen	Chronic low back pain
Markenson et al (299)	No	No	No	No	Oxycodone-CR	Osteoarthritis
Allan et al (300)	No	No	No	No	Fentanyl, morphine	Chronic low back pain
Matsumoto et al (301)	No	No	No	No	Oxymorphone	Chronic Osteoarthritis

13-22

strument. They concluded that the higher prevalence scores were associated with increased disability and patients were at greater risk for opioid misuse.

While similarities exist in all the criteria described, they differ to a great extent. The criteria developed by Atluri and Sudarshan (324) and evaluated by Manchikanti et al (322, 323) consistently showed three criteria to be diagnostic of opioid misuse or abuse, including: excessive opiate needs, deception or lying to obtain controlled substances, and doctor shopping. In an elaborate evaluation by Atluri and Sudarshan (324), six criteria were identified which included focus on opioids, opioid overuse, other substance use, nonfunctional status, exaggeration of pain, and unclear pain etiology. However, all screening instruments do not agree. Portenoy (317) compiled a list of aberrant drug-related behaviors, which were divided into two risk categories. Among the strongly predictive behaviors identified were forging prescriptions, stealing or borrowing drugs from others, frequently losing prescriptions, and resisting changes to pain treatment despite adverse effects. Less predictive behaviors were aggressive complaining about the need for more drugs, drug hoarding, and unsanctioned dose escalation or other forms of noncompliance. With a similar list, Savage (318) suggested that opioid addiction might be revealed through such behaviors as unwillingness to taper opioids or try alternative pain treatments, decreased levels of function despite appropriate analgesia, and frequent requests for medication before renewal is due.

Based on the multiple criteria utilized and their validation, the following may be used to indicate potential abuse or inappropriate use of opioids in clinical practice: 1) excessive opioid needs; 2) deception or lying to obtain controlled substances; 3) doctor shopping; 4) nonfunctional status; 5) exaggeration of pain; and 6) prescription forgery.

7.3 Urine Drug Testing

Drug testing may be performed by either testing the urine, serum, or hair. However, urine is considered to be the best biologic specimen for detecting the presence or absence of certain drugs due to specificity, sensitivity, ease of administration, and cost. However, controversies exist regarding the clinical value of urine drug testing, partly because the most current methods are designed for, or adapted from, forensic or occupational deterrent-based testing for illicit drug use and are not necessarily optimized for clinical applications in chronic pain management. However, in chronic pain management, when used with an appropriate level of understanding urine drug testing can improve a physician's professional ability to manage therapeutic prescription drugs with controlled substances, and to diagnose substance abuse or appropriate intake of drugs, thereby leading to proper treatment.

In principle, urine drug tests can detect the parent drug and/or its metabolite(s) and, therefore, demonstrate recent use of prescription medications and illegal substances. For most clinical applications, initial testing is done with class-specific immunoassay drug panels that typically do not identify individual drugs within a class. However, this may be followed by a more specific technique such as a gas chromatography/mass spectometry (GC/MS) to identify, or confirm the presence, or absence, of a specific drug and/or its metabolite(s). Numerous differences exist between various tests and even among the testing laboratories and manufacturers of various rapid drug screen tests, including the number of drugs tested, cross-reactivity patterns, cut-off concentrations, and drug interferences. Consequently, clinicians should remember that the cut-off concentrations used for drugs in federally-regulated testing, particularly opioids, are too high to be of value in clinical practice. Federally-regulated testing includes the five drugs or drug classes tested for in federal employees and employees of federally-regulated industries. The five include marijuana, cocaine, opiates, PCP, and amphetamines/methamphetamines, with pre-determined cut-off levels with mandatory reconfirmation of results by GC/MS, along with split sample in chain of custody requirements. In contrast, non-regulated testing is used for many purposes, including monitoring patients clinically.

Table 11. *Summary description of key criteria in the literature*

Criteria by Atluri and Sudarshan (324)	Criteria by Chabal et al (81)	Criteria by Compton et al (319)	Criteria by Manchikanti et al (322)	Criteria by Savage (235)
Focused on opioids	Overwhelming focus on opiate issues during pain clinic visits, persistent beyond the third clinic treatment session	Belief of addiction by the patient	Excessive opiates needs	Unwillingness to taper opioids
Opioid overuse	The pattern of early refills (3 or more) or escalating drug use in the absence of an acute change in the medical condition	Increasing analgesic dose or frequency	Deception or lying to obtain controlled substance	Effective analgesia, but decreased function
Other substance use	Multiple telephone calls or visits with requests for more opiates, early refills, or problems associated with the opiate prescription	Route of administration preference	Doctor shopping	Early refills
Non-functional	Prescription problems, including lost medications, spilled medications, or stolen medications			
Exaggeration of pain	Opiates obtained from multiple providers, emergency rooms, or illegal sources			
Etiology of pain unclear				

In clinical practice, urine drug testing is used for accurate record keeping, to identify use of undisclosed substances, to uncover diversion or trafficking, and to determine appropriate intake of prescribed substances. There are typically two types of urine drug testing. These approaches used in proper combination can reduce cost, ensure accuracy, and improve efficiency. The two main types of urine drug testing methods are:

1) Immunoassay drug testing, either laboratory based or by rapid drug testing
2) Laboratory-based specific drug identification with GC/MS, high-performance liquid chromatography (HPLC), etc.

Immunoassays, which are based on the principle of competitive binding, use antibodies to detect the presence of a particular drug or metabolite in a urine sample. Immunoassay drug testing is provided either in the laboratory or by means of rapid drug testing at the point of service. An immunoassay's ability to detect drugs will vary according to the drug concentration in the urine and the assay's cut-off concentration. Any response above the cut-off is deemed positive and any response below the cut-off is negative. Further, immunoassays are subject to cross-reactivity. For example, tests for cocaine are highly predictive of cocaine use. By contrast, tests for amphetamine/methamphetamine are highly cross-reactive and are unreliable. They may detect other sympathomimetic amines such as ephedrine and pseudoephedrine and, therefore, are not very predictive for amphetamine/methamphetamine use. Further, standard tests for opiates are very responsive for morphine and codeine, but do not distinguish which is present. They also show a lower sensitivity for semisynthetic/synthetic opioids such as oxycodone, fentanyl, methadone, and buprenorphine–a negative response does not exclude use of these opioids. Specific immunoassay tests for semisynthetics/synthetic opioids may be available.

In contrast to immunoassays or rapid drug testing, laboratory-based specific drug identification is more sophisticated and expensive. Laboratory-based specific drug identification is needed to specifically confirm the presence of a given drug and to identify drugs not included in a screening test. Table 12 illustrates cut-off levels for various drugs detected by urine analysis. Ideally, in chronic pain management settings a panel for rapid drug screening should include not only opiates, but also oxycodone and methadone. In addition, the panel should include cocaine, marijuana, amphetamines and methamphetamines for illicit drugs, and benzodiazepines and barbiturates for other controlled substances. If a custom panel is not available, multiple tests may have to be performed as rapid drug screening. Since false-negatives and false-positives are possible, when questions arise, prior to taking any actions, a confirmatory test or no-threshold test must be performed in the laboratory.

Table 12. *Typical detection times for urine drug testing of common drugs of abuse*

Drug	Detection Time In Urine	Cutoff Level (ng/mL)
Morphine	1 to 3 days (2 wks)	300
Methadone	2 to 4 days (2 wks)	300
Hydrocodone	2 to 4 days (2 wks)	50
Oxycodone	2 to 4 days (2 wks)	100
Benzodiazepines	Up to 30 days	300
Barbiturates (short-acting)	2 to 4 days	300
Barbiturates (long-acting)	Up to 30 days	300
Marijuana (chronic use)	Up to 30 days	50
Cocaine (benzoylecgonine - cocaine metabolite)	1 to 3 days	300
Amphetamine or methamphetamine	2 to 4 days	1000

Note that detection times can vary considerably, depending upon acute versus chronic use, the particular drug used within a class, individual characteristics of the patient, and the method used to test for a substance.

Physicians should establish a policy regarding their response to a positive drug screen. This may include referral to an addictionologist or psychologist, or may result in the refusal to prescribe opioids. However, it usually does not warrant dismissal of the patient. Furthermore, a policy regarding inappropriate use of prescription drugs provided by the physician, as well as doctor shopping, also should be addressed systematically and consistently. Interpretation of drug screens must include knowledge of the opioid metabolites. For example, a urine screen positive for hydromorphone in a patient receiving hydrocodone reflects not drug abuse but the appropriate metabolism of hydrocodone. In the same way, since codeine is metabolized to morphine, a screen positive for morphine in a patient taking codeine would be expected. Physicians not familiar with the opioid metabolites have wrongly accused too many patients of drug abuse.

7.4 Periodic Review and Monitoring

7.4.1 Periodic Review

Periodic reviews should assess the medical diagnoses; psychological diagnoses; informed consent; treatment agreement; appropriate opioid therapy with or without adjuvant medications or with or without interventional techniques; pre and post intervention assessment of pain level and function; and reassessment of pain score and level of function.

Regular assessment of the patient along with the periodic review of the diagnosis is extremely important. Routine assessment of the "4 As" (analgesia, activity, aberrant behavior, and adverse effects) will help to direct therapy and support the pharmacologic actions taken.

Further assessment should be performed by periodic monitoring, utilizing drug screening tests, and urine drug testing.

7.4.2 Periodic Monitoring

At reasonable intervals, depending on the specific circumstances of a given patient, the physician should review the course of treatment and any new information about the etiology of the pain. Continuation or modification of therapy should depend on the physician's evaluation of progress towards stated treatment goals, such as a reduction in a patient's pain scores and improved physical and/or psychosocial function (i.e., ability to work, utilization of healthcare resources, activities of daily living, and quality of social life). If treatment goals are not be-

ing achieved despite medication adjustments, the physician should reevaluate the appropriateness of continued treatment with the current medications. The physician should monitor patient compliance in medication usage and related treatment plans.

7.4.3 Prescription Drug Monitoring

Prescription monitoring programs are changing as the result of recently enacted NASPER legislation that will assist physicians and pharmacists in identifying controlled substance abuse (1,2,5-9). While some existing monitoring programs intend to support state laws to ensure legitimate access to drugs, while preventing illegal diversion (7,9), many represent information collected to assist state law enforcement and regulatory agents in identifying and investigating illegal practices related to controlled substances.

NASPER legislation will allow for electronic sharing of information across state lines, with physicians and pharmacists as primary users of the system. State by state development of NASPER programs will allow for electronic sharing of information across state lines and will ultimately replace most of the current prescription monitoring programs. Current programs generally involve either use of multiple-copy prescriptions or electronic transmission. Multiple-copy prescription programs require physicians to use state-issued duplicate copy prescription pads that contain serial numbers. After a prescription is filled, one copy of the prescription form is sent to a state regulatory agency. However, in recent years these programs have increasingly been replaced by electronic variations that require pharmacists to transmit prescription information via computer to a designated state agency.

Physicians can use these prescription programs to their advantage in monitoring patients. Monitoring can be achieved by initial assessment followed by intermittent assessment of a patient's drug profile. However, if abuse is suspected or the physician's office receives complaints from family, friends, neighbors, law enforcement, appropriate action should be taken, along with frequent monitoring.

7.4.4 Periodic Education

Drug education for physicians, providers, and patients is crucial. While it appears that certain medications have revolutionized the treatment of chronic pain in the United States, physicians must balance medical need with the possibility of abuse and diversion, as well as the necessity to comply with state and federal regulations. It is obvious that healthcare practitioners are not only expected to prescribe medications when there is medical need and document appropriately, but they are also expected to prevent illegal diversion and identify drug abuse. Consequently, education is a critical component of any program to control the diversion of prescription drugs (326).

However, data shows that many physicians get little to no training regarding drug abuse (4, 9). A 1999 survey of primary care physicians found there was a general lack of training in medical schools about addiction and the signs of substance abuse (327). This survey revealed that 46.6% of physicians had difficulty discussing prescription drug abuse with patients, and only 32.1% carefully screened their patients for substance abuse (327). This leads to difficulty discussing substance abuse with patients and an inability to recognize the signs of addiction. Figure 8 shows that the majority of the physicians surveyed did not feel "very prepared" to diagnose substance abuse.

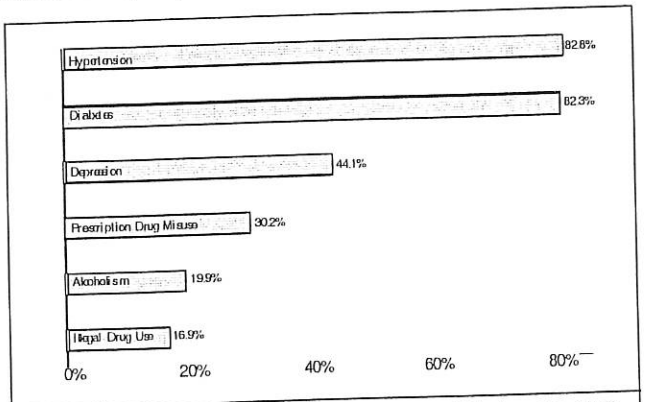

Fig. 8. *Conditions that physicians feel "very prepared" to diagnose, 1999*
Source: The National Center on Addiction and Substance Abuse at Columbia University, Missed Opportunity: National Survey of Primary Care Physicians and Patients on Substance Abuse (New York: CASA, 2000) (327)

The educational aspects have been improving gradually. The American Society of Interventional Pain Physicians (ASIPP) assists in preventing diversion while maintaining the availability of prescription drugs for medical treatment. ASIPP has devised guidelines for the use of controlled substances in the management of pain, which include information on how to conduct a comprehensive evaluation to select patients for drug therapy and how to use a "controlled substance agreement" as part of patient care. Other ASIPP activities have included actions and support leading to the passage of the National All Schedules Prescription Electronic Reporting Act (NASPER) for uniform drug monitoring programs across the states with interstate communication and physician access to the monitoring programs. In addition, the American Board of Interventional Pain Physicians has made a competency certification available for interested physicians. Other organizations involved in substance abuse training include the American Academy of Family Physicians which has taken steps to make physicians aware of practices such as doctor shopping, and the American Society of Addiction Medicine which conducts seminars and also provides certification in addiction management.

Additionally, several states have taken steps to educate physicians about prescription drugs.

7.4.5 Pill Counts

Random pill counts, along with urine drug testing and prescription monitoring, would greatly reduce controlled substance abuse and diversion. Pill counts are essential in patients suspected of abuse. However, these can also be performed randomly on high risk patients.

A pill count is performed by notifying the patient a day before or on the day of the

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patient's appointment that they are requested to bring any unused pills to the appointment. Inability to provide pills, or providing a reduced number, will indicate use beyond the prescription. Pill counts above expected ranges would indicate inappropriate intake. Recently, it has been reported that unsuspecting elderly patients may be selling their prescriptions of controlled substances to supplement their incomes (328).

8.0 Principles of Opioid Use

8.1 Introduction

In interventional pain management, patients may receive not only opioid analgesics, but also other controlled or non-controlled drugs. Further, patients may be receiving controlled substances as an adjunct to interventional techniques, as well as to manage comorbid psychiatric and psychological disorders. Thus, the effectiveness studies published may not apply in the majority of cases in interventional pain management. Indeed, controlled substances, particularly opioid analgesics, may be prescribed at lower doses to maintain functional status in conjunction with interventional techniques. It has also been shown that interventional techniques reduce psychological distress significantly once the pain improves. More likely than not, the requirement for opioids and adjuvant drugs may be reduced (329-336). Hence, interventional pain physicians probably should not compare the patients in their settings who are undergoing interventional techniques with others who are receiving drug therapy as a mainstay. Monotherapy, particularly with opioids, may be appropriate for only a small subgroup of those with chronic pain.

Gourlay et al (336) described a rational approach to the treatment of chronic pain with opioids. They described a pain and addiction continuum of substance use in pain patients leading to implementation of "universal precautions" in pain medicine. Ballantyne and Mao (89) also described the potential adverse consequences of prolonged opioid therapy, the clinical implications, and a suggested protocol and algorithmic approach for opioid therapy.

Model guidelines for the use of opioids for the treatment of pain by the Federation of Medical Boards, adapted by several states also provide guidance in the principles of opioid management (73).

8.2 Basic Philosophy

Principles for prescribing opioids must require a comprehensive evaluation (mandatory physical and optional psychological), appropriate documentation at regular intervals to assess the efficacy of therapy, with specific evaluation of their impact on functional status, degree of pain relief, identification and treatment of undesirable side effects, and monitoring for abuse behaviors. In addition, there must be adherence to a controlled substance agreement and with regulatory guidelines promulgated by various agencies. Figure 9 shows an algorithmic approach to patient evaluation and management. Table 13 (page 26) shows an algorithmic approach for chronic opioid therapy.

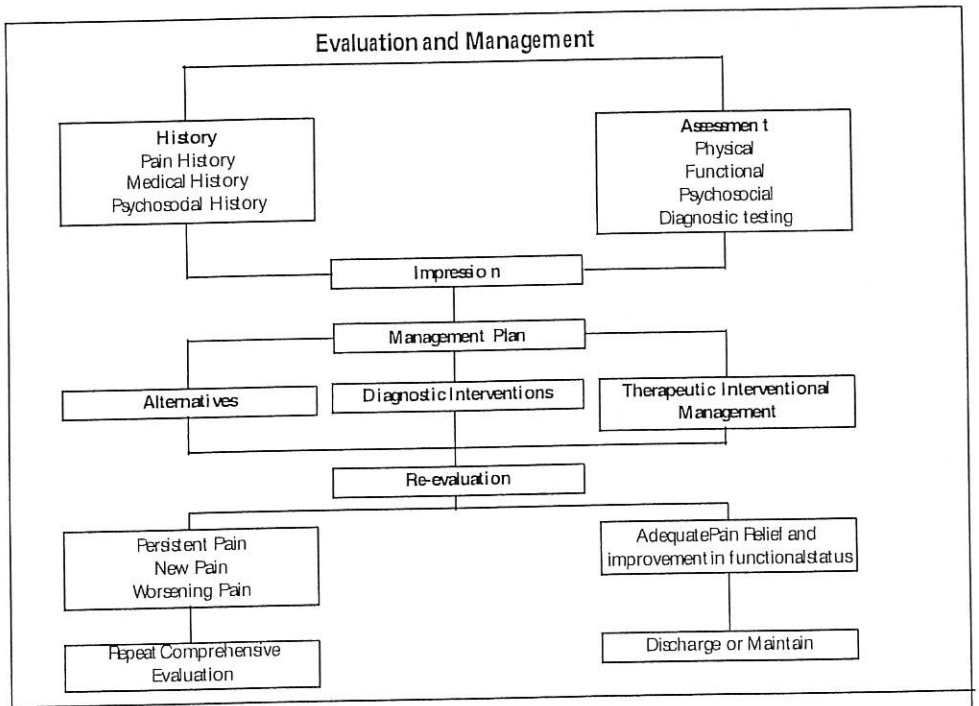

Fig 9. *A suggested algorithm for comprehensive evaluation and management of chronic pain.*

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8.3 Evaluation

Appropriate history, physical examination, and medical decision-making based on the initial evaluation of a patient's presenting symptoms are essential. Guidelines by the Centers for Medicare and Medicaid Services (CMS) provide various criteria for five levels of service (337-339). The three crucial components of evaluation and management services are: history, physical examination, and medical decision-making. Other components include counseling, coordination of care, nature of the presenting problem, and time required for face-to-face evaluation. While there are numerous techniques to evaluate a chronic pain patient, and these vary from physician to physician, institution to institution, and textbook to textbook, following the guidelines established by CMS will assist a physician in performing a comprehensive and complete evaluation while complying with regulations.

8.3.1 History

The history includes the chief complaint, history of the present illness, review of systems, and past, family, and/or social history (337-339).

History of the present illness is a chronological description of the development of a patient's present illness from the first sign and/or symptom. It includes multiple elements: location; quality, severity, duration, timing, context, and modifying factors; and associated signs and symptoms.

Review of systems is an inventory of body systems obtained through a series of questions seeking to identify signs and/or symptoms that the patient may be experiencing or has experienced.

Past, family, and/or social history is crucial for chronic pain patients who may be treated with opioids. It consists of a review of the past history of the patient, including past experiences, illnesses, operations, injuries, and treatment; family history, including a review of medical events in the patient's family, hereditary diseases, and other factors; and social history appropriate for age reflecting past and current activities.

Past history in interventional pain management includes history of past pain problems; motor vehicle, occupational, or non-occupational injuries; history of various pain problems; disorders such as arthritis, fibromyalgia, systemic lupus erythematosus; drug dependency, alcoholism, or drug abuse; and psychological disorders such as depression, anxiety, schizophrenia, suicidal tendencies, etc.

Family history is also important, and should include not only the history of different pain problems, including degenerative disorders, but also should include familial disorders, drug or chemical dependency, alcoholism, or drug abuse and psychological disorders such as depression, anxiety, schizophrenia, and suicidal tendencies, etc., specifically in first degree relatives.

Social history is also of crucial importance in administering opioids, including environmental information, education, marital status, children, habits, hobbies, occupational history, family support system, and recreational drug usage.

Table 13. *Ten step process: An algorithmic approach for long-term opioid therapy in chronic pain*

STEP I	Comprehensive initial evaluation
STEP II	Establish diagnosis ♦ X-rays, MRI, CT, neuro-physiological studies ♦ Psychological evaluation ♦ Precision diagnostic interventions
STEP III	Establish medical necessity (lack of progress or as supplemental therapy) ♦ Physical diagnosis ♦ Therapeutic interventional pain management ♦ Physical modalities ♦ Behavior therapy
STEP IV	Assess risk-benefit ratio ♦ Treatment is beneficial
STEP V	Establish treatment goals
STEP VI	Obtain informed consent and agreement
STEP VII	Initial dose adjustment phase (up to 8-12 weeks) ♦ Start low dose ♦ Utilize opioids, NSAIDs and adjuvants ♦ Discontinue due to □ Lack of analgesia □ Side effects □ Lack of functional improvement
STEP VIII	Stable phase (stable □ moderate doses) ♦ Monthly refills ♦ Assess for four As □ Analgesia □ Activity □ Aberrant behavior □ Adverse effect ♦ Manage side effects
STEP IX	Adherence monitoring ♦ Prescription monitoring programs ♦ Random drug screens ♦ Pill counts
STEP X	Outcomes ♦ Successful – continue □ Stable doses □ Analgesia, activity □ No abuse, side effects ♦ Failed – discontinue if □ Dose escalation □ No analgesia □ No activity □ Abuse □ Side effects □ Non-compliance

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8.3.2 Effect on Functional Status

Some of the aspects specific in controlled substance abuse and chronic pain include evaluation of effect of pain on physical and psychological function, such as activities of daily living.

8.3.3 Drug History

It is important to obtain a patient drug profile, including drug history and family history of drugs, and other chronic pain patients in the patient's social circles. It is also important to obtain a pre-drug screening prior to embarking on opioid therapy in conjunction with obtaining a patient's opinion with regards to the doses of controlled substances, the importance of adherence, and its monitoring.

8.4 Physical Examination

Physical examination involves general, musculoskeletal, and neurological examinations. Examination of other systems, specifically cardiovascular, lymphatic, skin, eyes and cranial nerves is recommended based on the presenting symptomatology (337-339).

8.5 Laboratory Studies

To complement the history and physical examination, a review of the records, either previous records or various investigations, must be obtained or new investigations must be ordered as appropriate. These include multiple radiological studies such as x-rays, MRIs, CT, bone scan, etc.; electrophysiologic studies such as EMG and nerve conduction studies; and blood work.

8.6 Psychological Evaluation

Psychological evaluation is an extension of the evaluation process similar to the laboratory evaluation, imaging techniques, electromyography and nerve conduction studies.

By definition, pain is a subjective description of the patient's perception of actual or potential tissue damage. The distinction between pain and suffering should be established. A patient may suffer due to pain, but may have other reasons for suffering as well. The assessment of a patient's overall condition should be made at the initial evaluation and frequently thereafter. It is the goal of the physician to assist in the relief of suffering, no matter the cause. Financial, emotional, mental, physical, and spiritual factors may contribute to the patient's suffering. Relief of the underlying causes of suffering, as well as the pain, will lead to optimal treatment and utilization of controlled substances.

8.7 Medical Decision Making and Treatment Plan

Medical decision making refers to the complexity of establishing a diagnosis and/or selecting a management option, including providing controlled substances to a patient, and is measured by three components: diagnosis/management options with a number of possible differential diagnoses and/or the number of management options; review of records/investigations, with number and/or complexity of medical records, diagnostic tests, and other information that must be obtained, reviewed, and analyzed; and risks of significant complications, morbidity and mortality, as well as comorbidities associated with the patient's presenting problem(s), the diagnostic procedures, and/or the possible management options (337-339).

Prior to embarking on a regimen of opioids, the physician must determine, through actual clinical trial or through patient records and history, that non-addictive medication regimens and/or interventional techniques have been inadequate or are unacceptable for solid, clinical reasons. If this information is not available entirely through the patient, a family conference may be helpful to evaluate the patient's integrity. However, because of HIPPA regulations, the ability to have family conferences may be limited. An extensive drug utilization history of the patient must be documented through previous medical records, state drug monitoring programs, and multiple other avenues.

Diagnostic interventional techniques will assist in making the proper diagnosis by following an algorithmic approach (12). It has been shown that in approximately 70% to 85% of patients with spinal pain an accurate diagnosis may not be determined in spite of the available history, physical examination, EMG nerve conduction studies, and radiological evaluation. With precise diagnostic interventional techniques, the chances of diagnosis may be improved substantially, and proper treatment may be offered (12,340-345).

Therapeutic interventional techniques also may be used as a monotherapy rather than using opioids for pain management and functional improvement. The effectiveness of various interventional techniques has been evaluated in systematic reviews (12,341,346-350) .

A written treatment plan should document objectives that will be used to evaluate treatment success, including pain relief and improved physical and psychosocial function, and should indicate if additional diagnostic tests, consultations, or treatments are planned. After starting treatment, the physician should carefully adjust the drug therapy to the individual medical needs of each patient. In the continuum of treatment, other modalities including interventional techniques, rehabilitation, and psychological therapy may be necessary depending on the etiology of pain and the extent to which pain is associated with physical, functional, and psychosocial impairment.

8.8 Consultation

To achieve treatment objectives, physicians should be willing to refer a patient for additional evaluation as clinically indicated. Special attention should be given to those patients who are at risk of misusing their medications and those whose living arrangements create a risk for medication misuse or diversion. The management of patients with a history of substance abuse or with a coexisting psychiatric disorder may require extra care, monitoring, documentation, and consultation with, or referral to, an addictionologist. The lack of well-trained psychologists and psychiatrists in many regions of the country may make this referral difficult to obtain. In many locations there are no clinically trained addiction specialists with whom to collaborate.

8.9 Informed Consent and the Controlled Substance Agreement

At the outset, the physician should discuss the risks and benefits of the use of controlled substances with the patient or surrogate, including the risk of tolerance and drug dependence. It is advisable to employ the use of a written agreement between physician and patient outlining patient responsibilities. Agreements are helpful, specifically if the patient is determined to be at high risk for medication abuse or has a history of substance abuse. Possible items of a controlled substance agreement between a physician and patient include:

1. One prescribing doctor and one

designated pharmacy
2. Urine/serum drug screening when requested
3. No early refills and no medications can be called in. If medications are lost or stolen, then a police report could be required before considering additional prescriptions.

The reasons for which opioid drug therapy may be discontinued should be delineated, such as violation of a documented doctor/patient agreement. Additional items to be included in an agreement are listed in Figure 10.

9.0 Documentation and Medical Records

The physician should keep accurate and complete medical records which include all aspects of interventional pain management and medical care. These comprise, but are not limited to:

- The medical history and physical examination
- Diagnostic, therapeutic, and laboratory results
- Evaluations and consultations
- Treatment objectives
- Discussion of risks, benefits, and limitations of treatments
- Details of different treatments and medications, including date, type, dosage, and quantity prescribed
- Instructions to the patient
- Periodic reviews of outcomes, including documentation of functional status, preferably using validated tools

Records should remain current and be maintained in an accessible manner and readily available for review, not only for the physician and other members of the practice, but also the authorities.

To be in compliance with controlled substance laws and regulations required to prescribe, dispense, or administer controlled substances, the physician must have an active license in the state and comply with applicable federal and state regulations. Various boards have published regulations and recommendations for prescribing controlled substances. Physicians are advised to refer to these regulations for their respective state.

Physicians, under all circumstances, except for unavoidable emergencies, should not prescribe scheduled drugs for themselves, immediate family, or staff.

The following criteria should be considered carefully in providing controlled substances:

1. Complete initial evaluation, including history and physical examination
2. Psychological evaluation
3. Physiological and functional assessment, as necessary and feasible
4. Definition of indications and medical necessity.
   - Pain of moderate-to-severe degree
   - Suspected organic problem
   - Failure to respond to non-controlled substances, adjuvant agents, physical therapy, and interventional techniques
   - Patients with interventional techniques as primary modality and controlled substance drugs as a second line treatment.
   - Responsiveness to prior interventions with improvement in physical and functional status for continued management, with or without interventions, must be documented.
   - For non-opioid controlled substances, appropriate documentation of psychological disorders should be maintained.
   - Continued opioid prescriptions require monitoring of:
     - Analgesia
     - Activity
     - Aberrant behavior
     - Adverse effects
5. Adherence to the controlled substance agreement with the patient understanding the risks and benefits of controlled substances and the policy and regulations of the practitioner, including controlled substances being prescribed by only one practitioner and being obtained from only one pharmacy.
6. Monitoring for drug abuse or diversion should be routine and, if confirmed, referral to rehabilitation centers may be made, along with termination of prescriptions for controlled substances.

10.0 Key Points

1. Opioid guidelines for the treatment of chronic non-cancer pain are developed to improve quality and appropriateness of care, improve patient access, improve patient quality of life, improve efficiency and effectiveness, and achieve cost containment by improving the cost-benefit ratio.
2. Rationalization and importance of these guidelines derives from the fact that most available evidence documents a wide degree of variance in the prescribing patterns of opioids for chronic pain. The strength of available evidence for the use of opioids for chronic non-cancer pain remains Limited, Level IV.
3. Opioids are extensively used in managing chronic pain.
4. There is significant evidence of opioid abuse in conjunction with or without illicit drugs.
5. Abuse terminology is variable. This document attempts to standardize and provide common sense definitions.
6. Opioid pharmacology is variable but understanding it is essential to proper management of patients.
7. Among the rules of opioid administration, comprehensive evaluation and diagnostic assessment are crucial, including diagnosis by interventional techniques.
8. Establishing goals of treatment and using a controlled substance agreement are essential in the practice of pain management with opioids.
9. Periodic review of the patient on opioids is essential, using appropriate adjustments, with routine assessment of analgesia, activity, aberrant behavior, and adverse effects.
10. Documentation is essential, including the need to keep accurate and complete medical records with all the essential elements to provide proper patient care and also meet regulatory and legal requirements.

We are committed to doing all we can to treat your chronic pain condition. In some cases, controlled substances are used as a therapeutic option in the management of chronic pain, which is strictly regulated by both state and federal agencies. This agreement is a tool to protect both you and the physician by establishing guidelines, within the laws, for proper and controlled substance use. The words "we" and "our" refer to the facility and the words "I," "you," "me," or "my" refer to you, the patient.

1. All controlled substances must come from the physician whose signature appears below or, during his/her absence, by the covering physician, unless specific authorization is obtained for an exception. I understand that I must tell the physician whose signature appears below or, during his/her absence, the covering physician, all drugs that I am taking, have purchased, or have obtained, even over-the-counter medications. Failure to do so may result in drug interactions or overdoses that could result in harm to me, including death. I will not seek prescriptions for controlled substances from any other physician, healthcare provider, or dentist. I understand it is unlawful to be prescribed the same controlled medication by more than one physician at a time without each physician's knowledge. I also understand that it is unlawful to obtain or to attempt or obtain a prescription for a controlled substance by knowingly misrepresenting facts to a physician, or his/her staff, or knowingly withholding facts from a physician or his/her staff (including failure to inform the physician or his/her staff of all controlled substances that I have been prescribed).

2. All controlled substances must be obtained at the same pharmacy, where possible. Should the need arise to change pharmacies, our office must be informed. The pharmacy that you have selected is:

   _____ phone _____

3. You may not share, sell, or otherwise permit others, including spouse or family members, to have access to any controlled substances that you have been prescribed.

4. Unannounced urine or serum toxicology specimens may be requested from you, and your cooperation is required. Presence of unauthorized substances in urine or serum toxicology screens may result in your discharge from this facility.

5. I will not consume excessive amounts of alcohol in conjunction with controlled substances. I will not use, purchase, or otherwise obtain any other legal drugs except as specifically authorized by the physician whose signature appears below or, during his/her absence by the covering physician, as set forth in Section 1 above. I will not use, purchase or otherwise obtain any illegal drugs, including marijuana, cocaine, etc. I understand that driving while under the influence of any substance, including a prescribed controlled substance, or any combination of substances (e.g., alcohol and prescription drugs) which impairs my driving ability, may result in DUI charges.

6. Medications or written prescriptions may not be replaced if they are lost, stolen, get wet, are destroyed, left on an airplane, etc. If your medication has been stolen it will not be replaced unless explicit proof is provided with direct evidence from authorities. A report narrating what you told authorities is not enough.

7. Early refills will not be given. Renewals are based upon keeping scheduled appointments. Please do not phone for prescriptions after hours or on weekends.

8. In the event you are arrested or incarcerated related to legal or illegal drugs (including alcohol), refills on controlled substances will not be given.

9. I understand that failure to adhere to these policies may result in cessation of therapy with controlled substances prescribed by this physician and other physicians at the facility and that law enforcement officials may be contacted.

10. I affirm that I have full right and power to sign and be bound by this agreement, and that I have read it and understand and accept all of its terms. A copy of this document has been given to me.

_____
Patient's full name

_____ _____
Patient's signature Date

_____ _____
Physician's signature Date

Fig 10. *Sample Controlled Substance Agreement*
Adapted from Pain Management Center of Paducah, Paducah, KY (Courtesy of Laxmaiah Manchikanti, MD)

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To: Senate Public Health and Welfare Committee

From: Jerry Slaughter
Executive Director

Subject: HB 2649; concerning the pain patient's bill of rights

Date: March 16, 2006

The Kansas Medical Society appreciates the opportunity to submit the following comments today on HB 2649, the pain patient's bill of rights. We support greater awareness and education on the treatment of pain by both health care providers and patients alike. We are in support of the goals of this bill, but we still have some concerns about how it will impact the treatment of patients with pain. The appropriate assessment and treatment of pain can be very challenging for all involved, and it is important that we not do anything with this legislation that complicates an already difficult clinical situation.

First, we would like to point out to the Committee that there already exist two clear statements of policy on this topic that serve as guidance for the health care professions. In 1998 the Kansas State Board of Healing Arts adopted the *Guidelines for the Use of Controlled Substances for the Treatment of Pain*, which can be found at: http://www.ksbha.org/misc/painmgmt.html . Then, in 2002 the Boards of Healing Arts, Nursing and Pharmacy adopted the *Joint Policy Statement of the Boards of Healing Arts, Nursing and Pharmacy on the Use of Controlled Substances for the Treatment of Pain*, which may be accessed at: http://www.ksbha.org/misc/jointpainmgmt.html . Both statements represent reasoned, clinically appropriate guidelines for health care professionals who take care of patients with pain.

Originally, this bill would have created a lengthy list of "rights" that patients in pain would be entitled to. Our concern with the original version of the bill was that the creation of new legal "rights," and the corresponding legal duties on physicians, would actually make providing appropriate care to patients with pain more problematic. We heard from numerous physicians who treat patients with pain, that the bill would result in some patients using it to pressure physicians to prescribe controlled substances for them. Physicians feared that they would be put in the position of being threatened or compelled to treat everyone who presents to the office or hospital emergency department with pain medications, even if other non-pharmacologic treatment modalities were more clinically appropriate, or if no treatment at all were indicated. The reality is that there are a small, but significant, number of patients who will use a well-intentioned expression of legislative intent such as this to gain access to controlled substances, either for their own individual use, or for diversion to others.

Senate Public Health & Welfare Committee
Date: March 16, 2006
Attachment # 14

We supported the inclusion of the House committee amendments that you find in the bill. We believed the House amendments made the bill more workable, and added clarity to the legislation. However, we have continued to hear from physicians around the state that the bill, as amended, will still create problems. The House amendments in New Section 2 were designed to eliminate concerns that the legislation conferred new legal rights on patients, and imposed new legal duties on practitioners. However, physicians are still concerned that the language in that section could have the same effect as the original language in the bill. For example, there is concern that the language in subsection (c) of New Section 2, on page 2, lines 35-39, will require physicians to refer to pain specialists every patient that they don't prescribe controlled substances to, even when such a prescription is not clinically indicated. At a minimum, we would ask you to delete that subsection.

We are also concerned with the possible abuse, or misuse, of the language in subsection (b): *"A person suffering from pain should have* ***access to and expect proper…treatment*** *of such person's pain...."* Again, this is well-intentioned language that could be used by some to demand access to controlled substances, even when it is not clinically indicated.

In summary, we are in conceptual support of the intent of the bill, but we are very concerned about how, in the real world, its provisions will play out. We would be more than willing to meet with the stakeholders in this issue and continue to work on language that advances the goals of the bill without creating problems that could actually make the assessment and treatment of pain more problematic. We would urge the Committee to not take action on this measure until the groups have had a chance to meet and consider appropriate alternatives. Thank you for considering our comments.

Kansas Advocates for Better Care

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HB 2649, "pain patient's bill of rights"

March 16, 2006

Honorable Chairman Barnett
and Committee Members:

Kansas Advocates for Better Care is supportive of HB 2649.

Kansas Advocates for Better Care (KABC) is a statewide non-profit organization of consumers that advocates for quality long-term care. It has been assisting/guiding consumers for more than 30 years as they try to understand and make use of the complex long-term care system of services.

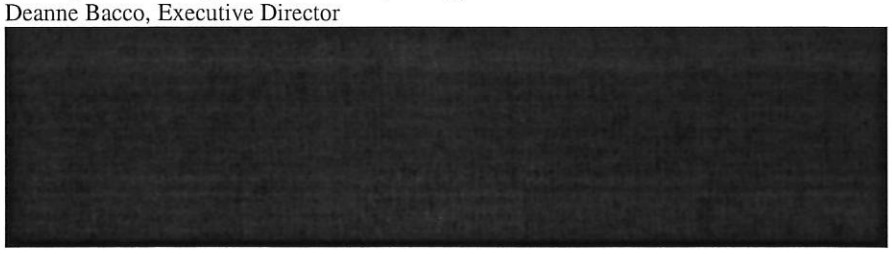
Residents in long-term care settings are only part of the population that is concerned with pain relief. The prevalence of pain in frail elders living in nursing homes has been a recognized indicator of quality for several years by the federal government Centers for Medicare and Medicaid Services. The following facts are from their Quality Indicators identified on their website. On January 25, 2006 they showed that the average percent of nursing home residents in Kansas who have moderate to severe pain was 9% while the national average was 6%. As well, the percent of short-stay nursing home residents in Kansas who had moderate to severe pain was 26% while the national average was 23%.

In the early 2000s the Robert Wood Johnson Foundation supported a major national effort to educate the population about pain and pain management. They even promoted the concept of calling "pain" the fifth vital sign.

Kansas has a recognized expert on pain management, Dr. Robert Twillman, who has spent countless hours making presentations across the state to help Kansans understand pain and how to get pain relief.

HB 2649 provides a final confirmation for Kansans that their pain should be acknowledged and taken seriously by health care professionals, family members or other legally authorized persons.

Thank you for this opportunity to testify in support of HB 2649.
Deanne Bacco, Executive Director



Senate Public Health & Welfare Committee

Date: March 16, 2006

Attachment #15

Testimony on HB 2649 to the
Senate Public Health and Welfare Committee

March 16, 2006

Thank you for the opportunity to submit this testimony today in support of HB 2649, the Pain Patient's Bill of Rights. There is growing awareness across America for the need for legislation of this type to combat the government, and particularly the DEA's, crusade against physicians who prescribe opiate pain medication.

The Cato Institute, in June of 2005, published a document detailing the "DEA's painkiller campaign [which] has cast a chill over the doctor-patient candor necessary for successful treatment." The Institute goes on to state in their report *Treating Doctors as Drug Dealers: The DEA's War on Prescription Painkillers,* executive summary attached, that this campaign against doctors who prescribe opiate pain killers "has resulted in the pursuit and prosecution of well-meaning doctors. It has also scared many doctors out of pain management altogether, and likely persuaded others not to enter it, thus worsening the already widespread problem of under-treated or untreated chronic pain."

As you may already be aware, in August 2004, the Drug Enforcement Administration issued guidelines for physicians regarding prescription of pain medication. According to an Associated Press report carried by the Wisconsin State Journal on Aug. 12, 2004 ("Doctors Get Guidance On Painkillers"), "Many doctors hesitate to prescribe narcotics, which are heavily regulated because they can be abused by addicts. The guidelines issued Wednesday, written by leading pain specialists together with the DEA, stress that the drugs are safe for the proper patient - -- and pledge that doctors won't be arrested for providing legitimate therapy."

The key message from the DEA guidelines: "These are legitimate treatments. They're essential for good medical care," said Dr. Russell Portenoy, pain chief at New York's Beth Israel Medical Center and a well-known pain specialist, June Dahl, a UW-Madison professor of pharmacology, called the guidelines "a great step toward reducing the barriers" to the treatment of severe pain. She added that doctors have been reluctant to give adequate doses because of "excessive fear" they might be investigated. "It's amazing how much confusion there still is. There is a reluctance to give adequate doses. It kind of seems unbelievable that there is a reluctance to treat people who are dying, especially since there's no evidence that you can get addicted."

Then in an abrupt about-face, the DEA withdrew the guidelines in October of 2004. Guidelines they had spent four years developing with the University of Wisconsin's Pain and Policy Studies Group. Dr. David Joranson, head of the University of Wisconsin Group, was quoted by the Wisconsin State Journal at the time stating the "DEA's abrupt withdrawal of support for the [Guidelines] without consulting with coauthors about their concerns, raises questions about what advisory role, if any, the pain management community can expect to have with DEA." The agency's changes, he says, "are likely to interfere in medical practice and pain management."

According to the Washington Post, "The DEA's abrupt turnaround appeared to have been triggered when defense lawyers tried to introduce the new Guidelines in the trial of Dr.

(William) Hurwitz" -- a Virginia pain specialist accused of overprescribing. Shortly after the Guidelines were withdrawn, the US prosecutor successfully petitioned the court to exclude them as evidence. In the Pain Guidelines, the doctors and the DEA had agreed that the government should stop investigating doctors like Hurwitz simply for being active in pain management -- and stop prosecuting those few who followed the recommendations but unwittingly prescribed opiates to deceitful patients. The DEA arbitrarily reversed that agreement.

In January of 2005, the National Association of Attorney Generals sent the attached letter to DEA Administrator Karen Tandy expressing concern over the withdrawal of the Pain Guidelines. Thirty AGs, including Kansas Attorney General Phill Kline, expressed "concern about recent DEA actions with respect to prescription pain medication policy." They went on to write, " Having consulted with your Agency about our respective views, we were surprised to learn that DEA has apparently shifted its policy regarding the balancing of legitimate prescription of pain medication with enforcement to prevent diversion, without consulting those of us with similar responsibilities in the states. We are concerned that state and federal policies are diverging with respect to the relative emphasis on ensuring the availability of prescription pain medications to those who need them."

Drug control policies, sometimes referred to as the "war on drugs" were intended to protect the public from the harmful effects of illicit drug use and abuse. In this case, these policies have adversely impacted the very people who rely on controlled substances to mange chronic pain. The government's failure to win the war on drugs should not keep doctors from performing their role in patient care. This legislation is necessary to protect patients and doctors from the unintended consequences of the DEA's politically-motivated withdrawal of the Pain Guidelines and continued prosecution of doctors who prescribe pain medication to patients with legitimate needs. I urge you to pass onto the full Senate for consideration the Pain Patient's Bill of Rights, HB 2649.

Thank you for the opportunity to submit this written testimony.

Laura A. Green
Executive Director
Drug Policy Forum of Kansas
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The Drug Policy Forum of Kansas was founded in 2005 to promote innovative policies and approaches to reduce the harms of both drug use and drug prohibition, and to increase public and political debate and support for cost effective and humane alternatives to the current criminal justice approach to drug policy.

Policy Analysis
No. 545 June 16, 2005

Routing

Treating Doctors as Drug Dealers
The DEA's War on Prescription Painkillers

by Ronald T. Libby

Executive Summary

The medical field of treating chronic pain is still in its infancy. It was only in the late 1980s that leading physicians trained in treating the chronic pain of terminally ill cancer patients began to recommend that the "opioid therapy" (treatment involving narcotics related to opium) used on their patients also be used for patients suffering from nonterminal conditions. The new therapies proved successful, and prescription pain medications saw a huge leap in sales throughout the 1990s. But opioid therapy has always been controversial. The habit-forming nature of some prescription pain medications made many physicians, medical boards, and law enforcement officials wary of their use in treating acute pain in nonterminal patients. Consequently, many physicians and pain specialists have shied away from opioid treatment, causing millions of Americans to suffer from chronic pain even as therapies were available to treat it.

The problem was exacerbated when the media began reporting that the popular narcotic pain medication OxyContin was finding its way to the black market for illicit drugs, resulting in an outbreak of related crime, overdoses, and deaths. Though many of those reports proved to be exaggerated or unfounded, critics in Congress and the Department of Justice scolded the U.S. Drug Enforcement Administration for the alleged pervasiveness of OxyContin abuse.

The DEA responded with an aggressive plan to eradicate the illegal use or "diversion" of OxyContin. The plan uses familiar law enforcement methods from the War on Drugs, such as aggressive undercover investigation, asset forfeiture, and informers. The DEA's painkiller campaign has cast a chill over the doctor-patient candor necessary for successful treatment. It has resulted in the pursuit and prosecution of well-meaning doctors. It has also scared many doctors out of pain management altogether, and likely persuaded others not to enter it, thus worsening the already widespread problem of undertreated or untreated chronic pain.

Ronald T. Libby is a professor of political science and public administration at the University of North Florida.

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January 19, 2005

Karen P. Tandy
Administrator
Drug Enforcement Administration
2401 Jefferson Davis Highway
Alexandria, VA 22301

Dear Ms. Tandy:

We, the undersigned Attorneys General, write to express our concern about recent DEA actions with respect to prescription pain medication policy and to request a joint meeting with you. Having consulted with your Agency about our respective views, we were surprised to learn that DEA has apparently shifted its policy regarding the balancing of legitimate prescription of pain medication with enforcement to prevent diversion, without consulting those of us with similar responsibilities in the states. We are concerned that state and federal policies are diverging with respect to the relative emphasis on ensuring the availability of prescription pain medications to those who need them.

Subsequent to DEA endorsement of the 2001 Joint Consensus Statement supporting balance between the treatment of pain and enforcement against diversion and abuse of prescription pain medications, the National Association of Attorneys General (NAAG) in 2003 adopted a Resolution Calling for a Balanced Approach to Promoting Pain Relief and Preventing Abuse of Pain Medications (copy attached). Both these documents reflected a consensus among law enforcement agencies, health care practitioners, and patient advocates that the prevention of drug abuse is an important societal goal that can and should be pursued without hindering proper patient care.

The *Frequently Asked Questions and Answers for Health Care Professionals and Law Enforcement Personnel* issued in 2004 appeared to be consistent with these principles, so we were surprised when they were withdrawn. The Interim Policy Statement, "Dispensing of Controlled Substances for the Treatment of Pain" which was published in the Federal Register on November 16, 2004 emphasizes enforcement, and seems likely to have a chilling effect on physicians engaged in the legitimate practice of medicine. As Attorneys General have worked to remove barriers to quality care for citizens of our states at the end of life, we have learned that adequate pain management is often difficult to obtain because many physicians fear investigations and enforcement actions if they prescribe adequate levels of opioids or have many patients with prescriptions for pain medications. We are working to address these concerns while ensuring that individuals who do divert or abuse drugs are prosecuted. There are many nuances of the interactions of medical practice, end of life concerns, definitions of abuse and addiction, and enforcement considerations that make balance difficult in practice. But we believe this balance is very important to our citizens, who deserve the best pain relief available to alleviate suffering, particularly at the end of life.

We understand that DEA issued a "Solicitation for Comments on Dispensing of Controlled Substances for the Treatment of Pain" in the Federal Register yesterday. We would like to discuss these issues with you to better understand DEA's position with respect to the practice of medicine for those who need prescription pain medication. We hope that together we can find ways to prevent abuse and diversion without infringing on the legitimate practice of medicine or exerting a chilling effect on the willingness of physicians to treat patients who are in pain. And we hope that state and federal policies will be complementary rather than divergent.

Lynne Ross, Executive Director of NAAG, will contact you soon to arrange a meeting at a mutually agreeable time, hopefully in March when Attorneys General will be in Washington, DC to attend the March 14-16 NAAG Spring Meeting. We hope to meet with you soon.

Thank you.

Sincerely,

WA Edmondson

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Attorney General of Oklahoma

Attorney General Gregg Renkes
Attorney General of Alaska

Attorney General Terry Goddard
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Attorney General of Iowa

Attorney General Phill Kline
Attorney General of Kansas

Attorney General Gregory D. Stumbo
Attorney General of Kentucky

Attorney General Charles Foti
Attorney General of Louisiana

Attorney General Steven Rowe
Attorney General of Maine

Attorney General Joseph Curran Jr.
Attorney General of Maryland

Attorney General Michael A Cox
Attorney General of Michigan

Attorney General Mike Hatch
Attorney General of Minnesota

Attorney General Jeremiah Nixon
Attorney General of Missouri

Attorney General Mike McGrath
Attorney General of Montana

Attorney General Jon Bruning
Attorney General of Nebraska

Attorney General Patricia Madrid
Attorney General of New Mexico

Attorney General Wayne Stenehjem
Attorney General of North Dakota

Attorney General Hardy Myers
Attorney General of Oregon

Attorney General Roberto Sánchez Ramos
Attorney General of Puerto Rico

Attorney General Patrick C. Lynch
Attorney General of Rhode Island

Attorney General Henry McMaster
Attorney General of South Carolina

Attorney General Paul Summers
Attorney General of Tennessee

Attorney General Mark Shurtleff
Attorney General of Utah

Attorney General William Sorrell
Attorney General of Vermont

Attorney General Darrel McGraw
Attorney General of West Virginia

Testimony in support of HB 2649

Phyllis Zorn

On Dec. 26, 2004, I took my daughter, Miranda Zorn, to the emergency room at Hays Medical Center for treatment of what we suspected was strep throat. Diagnosing a viral infection, the attending physician ordered an injection of SoluMedrol to ease Miranda's symptoms.

The injection intended to usher in relief for Miranda instead ushered in the nightmare that brings us to speak to you today. The needle was unsterile and within only a few days an abscess developed that later proved to be a staph aureus infection. The abscess was 8 centimeters across. That is the size of the entire palm of my hand.

On Saturday, Jan. 8, after one return trip to the emergency room and two visits to her physician's office, the abscess began oozing pus. We returned to the emergency room to have the drainage cultured.

On Monday, Jan. 10, Miranda's physician read the preliminary lab results, canceled her appointment with him and scheduled her to see his partner, an infectious disease specialist. Thus the partner took over her treatment for the abscess.

That afternoon, the doctor lanced and drained the abscess. He anesthetized only the incision area in preparation for the operation. He did not anesthetize deep tissue. His records note that about 100 cc of pus was drained from the incision. The abscess cavity, which was measured the following day in the first of 18 visits to the hospital's special nursing unit, was 3.6 centimeters deep, 2 centimeters long and 1 centimeter wide.

I want to emphasize that **only** the incision area had been anesthetized. Although

Miranda felt only pressure as the initial incision was made, when the doctor made a second cut to be able to reach deeper into the abscess, that cut was made without any anesthesia. Also done without anesthesia was the process of repeatedly reaching inside the abscess with his finger to pull out pus and dead tissue.

The process was extremely painful for Miranda, since the area of inflammation was so large and the surgery extended far past the anesthetized surface. In reaction to the pain, Miranda first complained, then began to cry. She cried throughout the procedure and pleaded with the doctor to make the pain stop. I asked him if there was something more he could do to ease her pain, but he told me there wasn't because the abscess had already been cut open.

It wasn't until months later, in speaking to another doctor for an article about under-treatment of pain and the reasons doctors are overly cautions about treating pain, that the other doctor explained all the options that existed in Miranda's specific circumstances. Those options included additional injections, intravenous pain medications, bringing in an anesthesiologist and taking her to the operating room for general anesthesia if lesser measures were unsuccessful. Twice the doctor being interviewed told me that what happened that day, as well as the following day when Miranda's regular doctor directed the nurse to unpack, clean, measure and repack the wound without administering pain medication (a directive the nurse refused to follow), "did not comply with the standards of care." He further said under-treatment of pain is a disciplinary issue with the Kansas Board of Healing Arts.

I understand completely the threat a staph aureus abscess poses. In 1995, one

week before Christmas, my best friend, an otherwise healthy 34-year-old mother of four little girls, died from septicemia brought on by a staph aureus infection.

Knowing the threat Miranda's abscess posed, I comforted her throughout the operation so that she would comply with the procedure. Those of you who are parents will understand the depth of my own agony in watching my child suffer that day.

The doctor noted in his records, "the patient tolerated the procedure well."

I disagree.

I am grateful to the doctor for treating the abscess and thankful to have Miranda beside me today, but there was no reason for her to suffer so much during the surgery. Although public policy that existed before this legislation seemingly prohibits such painful procedures from being done without adequate pain relief, obviously existing public policy is not enough.

STATE OF KANSAS

DELIA GARCIA
REPRESENTATIVE, 103RD DISTRICT
SEDGWICK COUNTY
P.O. Box 48283
WICHITA, KANSAS 67201
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ROOM 272-W, CAPITOL BLDG.
TOPEKA, KANSAS 66612-1504
(785) 296-7650
1-800-432-3924

TOPEKA

HOUSE OF
REPRESENTATIVES

COMMITTEE ASSIGNMENTS
COMMERCE AND LABOR
HEALTH AND HUMAN SERVICES
JUDICIARY

Senate Committee on Health and Human Services
Testimony for **HB 2825**
March 16, 2006
By Representative Delia Garcia

Chairman Barnett, Vice Chairwoman Schmidt, Senator Haley, and Distinguished Committee Members:

Thank you for the opportunity to speak with you today in support of **HB 2825 w**hich provides for a mechanism to establish a voluntary, comprehensive data bank of available interpreters.

It was my honor to be a Committee Member of the Healthy Kansans 2010 along with Representative Peggy Mast during the interim in the summer and fall of 2005. In this collaborative effort with KDHE, and a part of this 25+ member committee of stakeholders, the concern of cultural competency and minority health arose in almost all the top areas of study. I was inspired to further research and collaborate on the idea of introducing a committee bill that asks for some form of organizational structure and framework to the healthcare interpreter resource community.

HB 2825 leads to greater safety and protection measures for all Kansans. It provides for this voluntary, comprehensive data bank of interpreters as a resource for Kansans in the health care field, not just the court system. I know I would not want a court interpreter translating for my knee surgery, if that were the case. This bill minimizes medical errors, while increasing the quality of care for Kansans, because these interpreters will know the medical terminology. Therefore, this bill will encourage people to seek out early services by having an interpreter in a safe environment. This could result in a decrease in some Medicaid funds and escalating emergency room visits.

I am excited that this bill demonstrates not only Kansas' commitment, but KDHE's commitment to Minority Health. In my home city of Wichita, the school district did a recent study that discovered between 58 and 64 different languages and dialects. There is definitely a need for access to a pool of interpreters. Other states are addressing this issue, including our neighboring state Missouri.

This bill is part of a national movement concerning this need, which states have been trying to meet for years. **HB 2825** complies with the Federal Law, *Title VI of Civil Rights Act of 1964* which

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promises "equal access to federally assisted programs and activities." I will refer to the KDHE power point on the *Limited English Proficiency: A guide to Compliance with OCR Regulations for Health Care Providers receiving Federal Financial Assistance from HHS.* This power point includes the emphasis on increasing protection and safety measures as a direct result of the happenings of other states. This bill does not re-invent the wheel, quite the contrary; it compliments what movement is going on and provides a measure of an organization structure to the health care services component that presently does not exist. **HB 2825** is one of many important measures in this health care setting. This bill further strengthens greater safety and protection, while serving useful guidance to other entities.

I strongly urge you to pass **HB 2825** favorably. Thank you for your attention to this very important matter.

Thank you,

Delia Garcia

Representative Delia Garcia

Delia Garcia

Kansas Association of the Deaf, Inc.

P.O. Box 10085
Olathe, Kansas 66051

Members of the Senate Public Health and Welfare Committee:

My name is Leonard Hall. I am President of KAD and also an attorney with the City of Olathe. I have been involved with the statutes and regulations involving interpreters under Kansas Commission for the Deaf and Hard of Hearing (KCDHH) since the statutes were written in the mid-1980s.

On February 21, 2006, I testified in favor with amendments for the original HB 2825. All parties agreed that there is a major need to provide for standards and databank of **Foreign Language Interpreters,** because there are no standards and databank for them in Kansas. We have standards for sign language interpreters under KCDHH.

At the last minute, a Substitute for HB 2825 was introduced which we were not aware of. It was a rush job with little time to draft the appropriate amendments for the substitute bill. However, the House committee agreed with us and directed us to work with the parties to draft an acceptable bill. Some changes were made but apparently several crucial amendments were left out in the very short time period to get the bill out of committee.

The important point is that KCDHH currently provides for rules and regulations for registration and certification for **Sign Language Interpreters** under K.S.A. 75-5391 et seq. KCDHH is currently providing evaluation and certification for over 500 Sign Language Interpreters across Kansas. In this room, the system is working and we have a sign language interpreter interpreting for me.

Apparently, KDHE and other parties in support of HB 2825 were unaware that KCDHH has a program for over 500 Sign Language Interpreters in drafting this bill.

The key purpose of this HB 2825 is to provide for a data bank and standards for interpreters to be under the jurisdiction of KDHE. However, Substitute HB 2825 provides for no distinction between the Foreign Language Interpreters to be under KDHE and the Sign Language interpreters to be under KCDHH.

Without any amendment to Substitute HB 2825, KDHE will be doing duplicate services that KCDHH is already providing for Sign Language Interpreters. There will be a lot of confusion of parties wanting to secure interpreters if two separate agencies are providing the same program for Sign Language Interpreters.

Across Kansas and United States, people and businesses usually referred to Foreign Language Interpreters and Sign Language Interpreters, so the amendments are drafted with the common usage.

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Under the proposed attached amendments, KDHE will provide new standards and a databank for Foreign Language Interpreters and KCDHH will continue to provide standards and regulations with a separate databank for Sign Language Interpreters.

One important point set out in the proposed amendments is removal of the definition of (a)(5) "Services, programs, and facilities", which the definition limited to programs for medical, health care or mental health care services. The purpose of removing this definition is to allow for the standards and databank for foreign language interpreters that can be used for many areas, including education, government services, etc. KDHE secretary will still has the right to limit standards and databank to medical, health care and mental health care services in adopting the regulations and rules, but should be given flexibility to go beyond the health area.

It is logical when setting standards for foreign language interpreters to apply them to any situation where an interpreter may be needed in Kansas. Why limit the standards and databank to the health area, when KDHE can provide such invaluable service to all Kansas entities.

KAD and other parties still support this bill as there is a major need for standards and databank for foreign language interpreters in Kansas.

I attached a copy of the amendments to the Bill and the language is provided below:

(a)(2) "Foreign Language Interpreter" means a person who is qualified to interpret effectively, accurately and impartially in any primary language other than English, except for sign language. "Sign Language Interpreter" means a person who provides interpreter services for deaf, hard of hearing, and speech impaired people as provided under K.S.A. 75-5391, et seq.

(a)(3) "Interpreter data bank" means a directory listing the names of individual interpreters by each of the following: Foreign Language Spoken or Sign Language, location and surname.

(a)(5) Delete definition for "Services, programs, and facilities" so that the data bank will be available to any service providers who can check for a list of foreign language interpreters.

(b)(1) Establish a data bank of available foreign language interpreters to assist clients in communication with providers of services, programs and facilities and to provide a link to Kansas Commission of the Deaf and Hard of Hearing for access to a data bank of available sign language interpreters; and

(b)(2) ….. rules and regulations establishing standards for foreign language interpreters, including, but not limited to …..

Session of 2006

Substitute for HOUSE BILL No. 2825

By Committee on Health and Human Services

2-22

AN ACT providing for establishment of a voluntary data bank of available interpreters for certain purposes and development of qualifications for interpreters.

Be it enacted by the Legislature of the State of Kansas:

Section 1. (a) As used in this section:

(1) "Available interpreter" means a person 18 or more years of age who reports possessing the experience, skills or other qualifications to fulfill the role of interpreter.

~~(2) "Interpreter" means a person who translates orally, in writing or by signing for parties requiring translation to facilitate communication when they do not share a language.~~

~~(3) "Interpreter data bank" means a directory listing the names of individual interpreters by each of the following: Language spoken, location and surname.~~

(4) "Secretary" means the secretary of health and environment.

~~(5) "Services, programs and facilities" means adult care homes, hospitals, local health departments, community mental health centers and other programs or facilities which provide medical, health care or mental health care services.~~

(b) The secretary shall:

~~(1) Establish a data bank of available interpreters to assist clients in communications with providers of services, programs and facilities; and~~

(2) adopt, with the advice of the advisory committee appointed pursuant to subsection (d), rules and regulations establishing standards for interpreters, including, but not limited to, a code of ethics which would ensure that interpreters provided impartial and unbiased translations which (A) reflect precisely what is said by all parties and (B) place persons with limited proficiency in the English language on an equal footing with persons who understand English.

(c) Nothing in this section shall be construed to require any interpreter to be included in the data bank provided for by this section or to require any client to use the services of an interpreter who is included in such data bank.

(d) The secretary, pursuant to K.S.A 75-5616, and amendments

(a)(2) "Foreign Language Interpreter" means a person who is qualified to interpret effectively, accurately and impartially in any primary language other than English, except for sign language. "Sign Language Interpreter" means a person who provides interpreter services for deaf, hard of hearing, and speech impaired people as provided under K.S.A. 75-5391, et seq.

(a)(3) "Interpreter data bank" means a directory listing the names of individual interpreters by each of the following: Foreign Language Spoken or Sign Language, location and surname.

(a)(5) Delete definition for "Services, programs, and facilities" so that the data bank will be available to any service providers who can check for a list of foreign language interpreters.

(b)(1) Establish a data bank of available foreign language interpreters to assist clients in communication with providers of services, programs and facilities and to provide a link to Kansas Commission of the Deaf and Hard of Hearing for access to a data bank of available sign language interpreters; and

(b)(2) ….. rules and regulations establishing standards for foreign language interpreters, including, but not limited to …..

thereto, shall appoint an advisory committee to consult with and advise the secretary on implementation of this section. The executive director of the commission for the deaf and hard of hearing, or the executive director's designee, shall be a member of the advisory committee.

(e) The secretary shall adopt such rules and regulations as necessary to implement the provisions of this section.

Sec. 2. This act shall take effect and be in force from and after its publication in the statute book.

KANSAS

RODERICK L. BREMBY, SECRETARY

KATHLEEN SEBELIUS, GOVERNOR

DEPARTMENT OF HEALTH AND ENVIRONMENT

Testimony on
Substitute House Bill 2825

To:
Senate Public Health and Welfare Committee

By:
Dr. Howard Rodenberg
Director, Division of Health
Kansas Department of Health and Environment

Date: March 16, 2006

Chairman Barnett and Members of the Committee, I am Howard Rodenberg, Director of the Division of Health of the Kansas Department of Health and Environment. Thank you for the opportunity to provide testimony in support of the Substitute for HB 2825. This bill provides for a mechanism to establish a voluntary data bank and directory of available interpreters to assist Kansans in obtaining meaningful access to needed health care.

It comes as no surprise to anyone in this room that Kansas has become a state of diversity. Fully 17% of us are Hispanic, African-American, Native American, or Asian. These segments of our population continue to grow, and new immigrants add to these vital segments of our communities. However, with a growing number of Kansans still learning the English language, health facilities and professionals across the state may have difficulty communicating with our newest residents. Our health care system is increasingly reliant upon bi-lingual persons to provide communication assistance that is culturally and clinically accurate, impartial, and effective. The intent of the bill is to support access to health care for individuals with limited English skills. This bill helps to meet our goals of reducing health disparities and enhancing healthcare provider cultural competency, two of the three key goals of our Healthy Kansans 2010 Project. We also envision this project as a "kickoff" for our new Office of Minority Health, as early success in an effort as important as this can translate into additional federal and private grant funding in the future.

KDHE is in support of the bill as revised. Our initial concern centered on the definition of "qualified interpreter." Under the terms of the revision, participation will be voluntary and the decision to seek inclusion in the data base will be based upon the individual's availability and self-reported possession of experience, education or training to fulfill the role of interpreter.

OFFICE OF THE DIRECTOR OF HEALTH
CURTIS STATE OFFICE BUILDING, 1000 SW JACKSON ST., STE. 300, TOPEKA, KS 66612-1368
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In the absence of a nationally recognized certification process for medical interpreters, we must assure within the statute that employers, clients, and the public understand that finding a person's name in the proposed resource directory is not endorsement by KDHE of the qualifications of any individual interpreter. We do believe that notation of the translator's obligation to translate to "the best of their ability" and the provision for adoption of a "code of ethics" underscores the seriousness of this task.

The new language clarifies that inclusion of an individual's name in this data bank does not imply that it is the only source or even the preferred source of interpreters. Hospitals, county health departments, and individual health care providers may have long-standing relationships with interpreter services, employees, or community volunteers who offer to help when language assistance is needed. This data bank is not intended to upset or supercede these relationships. The primary purpose is to provide a resource for those who, when faced with a problem of communication, currently do not know where to turn.

Thank you for the opportunity to support this bill. I'll be happy to respond to any questions you might have.

Kansas Commission on Disability Concerns

Testimony to Public Health and Welfare Committee
HB 2825; An act providing for a mechanism to establish a data bank of interpreters
March 16, 2006

Chairperson Barnett and members of the committee, I am Kerrie Bacon, Legislative Liaison for the Kansas Commission on Disability Concerns (KCDC). We are charged with providing information to the Governor, the Legislature, and to State agencies about issues of concern to Kansans with disabilities (K.S.A. 74-6706).

The Kansas Commission on Disability Concerns urges you to support HB 2825 with amendments proposed by the Kansas Association of the Deaf, Inc. There needs to be clarification between foreign language interpreters and sign language interpreters, especially since sign language interpreters are covered under Kansas statute already (K.S.A. 75-5391 et seq). We also support the removal of the definition of (a)(5) "Services, programs, and facilities", because it was limited to programs for medical, health care or mental health care services. This internet listing needs to be available to all public and private groups that can make use of interpreter services.

The commission is supportive of this bill with the proposed amendments and encourages you to recommend it favorably for passage to the full Senate.

Thank you for your time.

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American Heart Association.
Learn and Live℠

Heartland Affiliate
5375 SW 7th St.
Topeka, KS 66606
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(800) 242-8721
fax (785) 272-2425
www.americanheart.org

March 16, 2006

TO: Senate Committee on Public Health and Welfare

FROM: Linda J. De Coursey, Advocacy Director – Kansas

RE: HB 2825 – Mechanism established by KDHE for a data bank of interpreters and Standards for qualifications

Mr. Chairman and members of the Committee:

My name is Linda De Coursey and I am submitting written testimony on behalf of the American Heart Association in support of HB 2825. The proposed bill establishes a data bank of qualified interpreters to assist clients in communications with providers of services, programs and facilities under the Secretary of the Department of Health and Environment. Such facilities would provide services such as medical health care or mental health care.

The American Heart Association's mission is to reduce death and disability from cardiovascular disease and stroke. AHA has a goal to reduce cardiovascular disease and stroke by 25% by 2010. This goal can be achieve through: research and science, public and professional education programs and strengthening health care delivery.

One of our Cultural Health Initiatives strives to establish priorities and strategies to educate emerging populations to reduce cardiovascular disease and stroke disparities through programs, messaging, media, advocacy, and partnerships that reach out to and empower communities to live healthier lifestyles.

- Among Hispanics or Latinos 6.1 percent have heart disease, 14.5 percent have hypertension and 1.8 percent have had a stroke.
- Among the Asians, 5.4 percent have heart disease, 13.5 percent have hypertension and 2.2 percent have had a stroke.
- Among Native Hawaiians, 1.6 percent have heart disease, 14.5 percent have hypertension and 6.3 have had a stroke.
- The over all death rate for stroke was 40 percent in Hispanics, and 52.4 percent for Asian.

These statistics are shared with you because the aspect of improving access to care is an important one. Establishing an interpreter to assist clients in communications in medical arena could save a life. We ask your favorable consideration of HB 2825.

FOREIGN LANGUAGE INTERPRETER CONSORTIUM

Kansas Association of Interpreters
PO Box 14731
Lenexa, Kansas 66285
http://kai4terps.tripod.com

To: The Honorable James Barnett, Chairman and Honorable Members of the Senate Health and Human Services Committee
From: Gabriela Flores, Executive Committee Member, Foreign Language Interpreter Consortium of Kansas Association of Interpreters
Date: March 16, 2006

Subject: Proponent in Support of HB 2825

I am writing to express my sincere gratitude for this opportunity to support HB 2825. My name is Gabriela Flores. I am an active member of the Kansas Association of Interpreters, Foreign Language Interpreters Consortium. Over the last several years, our group has worked diligently to increase the competency and professionalism of interpreters in the local community, in order to ensure that limited English proficient (LEP) citizens and residents of the state of Kansas receive equal access to the legal and healthcare systems. Our work to develop awareness in the general community and to provide professional development opportunities for interpreters, minimizes the potential for discrimination and unequal treatment.

The need to develop a statewide registry of qualified and competent interpreters is critical. It would provide invaluable resources of qualified interpreters to statewide institutions that are struggling to comply with Title VI of the 1964 Civil Rights Act and the Executive Order #13166. By creating a statewide registry of Interpreters, this would ensure that LEP Kansans would receive fair and equitable access to services, delivered via a trained and competent interpreter.

This important legislation would equate to minimized liability for Kansas hospitals and clinics, improved quality of care and patient safety, as well as access to a fair and equitable legal system.

I strongly urge you to pass HB 2825 out favorably. Thank you for your attention to this very important matter.

LAWRENCE-DOUGLAS COUNTY HEALTH DEPARTMENT

200 Maine, Suite B
Lawrence, Kansas 66044-1357
Office: 785-843-3060 Fax: 785-843-3161
Clinic: 785-843-0721 Fax: 785-843-2930

Senate Committee on Health and Human Services
March 16, 2006
Written Testimony presented by
Nancy Jorn, MN, ARNP
Director of Maternal Child Health Field Services
Lawrence-Douglas County Health Department

Chairman Barnett and members of the committee, thank you for the opportunity to share comments on the proposal to establish a centralized interpreter database as proposed in House Bill 2825.

Over the past five years, the Lawrence-Douglas County Health Department has experienced a rapid increase in the number of English language learners seeking services from our agency. Currently, 20% of families served through our maternal and infant program do not speak English fluently. In surrounding urban counties, the proportion is even greater.

Clear communication with those using health services is critical to obtaining an accurate health history, providing health education and treatment, and assuring follow-through on the treatment plan. Unless bilingual health care professionals are available, it is essential to use an interpreter to provide health care services for those who do not speak English fluently.

Finding interpreters has presented a significant challenge for our agency, even in a university community where one finds more than the usual number of bilingual individuals.

Having established our own internal database of interpreters, we now find many other community health and social service providers turning to our agency for help finding interpreters. In the past two weeks, I have been contacted by our community mental health center and the local child care resource and referral agency, both seeking information on available interpretation services. We receive similar calls from physicians' offices working to communicate with their non-English speaking patients.

By providing a single point of contact for providers and a means for interpreters to make themselves known to those needing their services, a centralized, statewide data bank of interpreters would significantly aid those working throughout Kansas to provide quality health and social services for English language learners.

TO: The Honorable James Barnett, Chairman and Honorable Members of the Senate Health and Human Services Committee

FROM: Zach Campbell, Jewish Vocational Service trilingual employment specialist

DATE: March 16, 2006

SUBJECT: Proponent in Support of HB 2825

Thank you Chairman Barnett and honorable members of the Health & Human Services Committee for this opportunity to express my support of HB 2825. My name is Zach Campbell, and I am writing as a constituent of Representative Sue Storm, and on behalf of Jewish Vocational Service (JVS), where I am a trilingual employment specialist.

Through our Interpreter Services department, JVS has worked diligently to increase the competency and professionalism of interpreters in the local community through the development of an interpreter database and through offering a medical interpreter training program, Bridging the Gap®. Through our work to develop systems of culturally competent health care, our agency strives to ensure that residents of the state of Kansas receive equal access to the legal and healthcare systems, and our work minimizes the potential for discrimination and unequal treatment.

The need to develop a statewide registry of qualified and competent interpreters is critical. By creating a statewide registry of interpreters, this would ensure that limited English proficient Kansans would receive fair and equitable access to services, delivered through a trained and competent interpreter. This important legislation would equate to minimized liability for Kansas hospitals and clinics and improve quality of care and patient safety as well.

I strongly urge you to pass out favorably House Bill 2825. Should you have any questions, please feel to contact me at my office at 816-471-2808 ext. 1110. Thank You.

Sincerely,
Zach Campbell
Trilingual Employment Specialist
Jewish Vocational Service
1608 Baltimore, Kansas City, MO 64108
(816) 471 2808
zcampbel@jvskc.org <mailto:zcampbel@jvskc.org>
zachcampbell@gmail.com <mailto:zachcampbell@gmail.com>

To: The Honorable James Barnett, Chairman and Honorable Members of the Senate Health and Human Services Committee

From: Maria Cecilia Ysaac-Belmares, A+ Communications, Owner; Executive Committee Member, Foreign Language Interpreter Consortium of Kansas Association of Interpreters

Date: March 16, 2006

Subject: Proponent in Support of HB 2825

As a citizen of Kansas, I am writing to express my sincere gratitude for this opportunity to support HB 2825. My name is M. Cecilia Ysaac-Belmares. I am a Certified Spanish Language Court Interpreter by the Consortium for State Court Interpreter Certification and I have over 7 years of experience as a Medical Interpreter.

Over the last several years, our group has worked diligently to increase the competency and professionalism of interpreters in the local community, in order to ensure that limited English proficient (LEP) citizens and residents of the state of Kansas receive equal access to the legal and healthcare systems. Our work to develop awareness in the general community and to provide professional development opportunities for interpreters minimizes the potential for discrimination and unequal treatment.

The need to develop a statewide registry of qualified and competent interpreters is critical. It would provide invaluable resources of qualified interpreters to statewide institutions that are struggling to comply with Title VI of the 1964 Civil Rights Act and the Executive Order #13166. By creating a statewide registry of Interpreters, this would ensure that LEP Kansans would receive fair and equitable access to services, delivered via a trained and competent interpreter.

This important legislation would equate to minimized liability for Kansas hospitals and clinics, improved quality of care and patient safety, as well as access to a fair and equitable legal system.

I strongly urge you to pass HB 2825 out favorably. Thank you for your attention to this very important matter.

Honorable Chairman Barnett and honorable members of the Senate Health & Human Services Committee:

I would like to thank you for this opportunity to express my support for HB 2825. My name is Marcela Renna and I am a freelance Spanish interpreter in the Kansas City metropolitan area. I am a certified interpreter for federal and state courts. I am well aware of the need for trained and qualified interpreters in the medical and legal fields and I look forward to increasing the pool of accredited medical interpreters to better serve the minority populations in our city.

Having knowledgeable interpreters would benefit Latinos and other minority groups by allowing them to interact with their health care providers and would assure proper communication during these medical situations, which are of vital importance to the patients' lives.

I urge you to pass out favorably House Bill 2825.

Thank You.
Sincerely,
Marcela Renna
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913.406.5311 (cell)
913.383.0401 (fax)
worldlanguagesinc@yahoo.com

To: Hon. James Barnett, Chairman and Hon. Health Committee Members

Re: HB 2825 Health Care Interpreters in Kansas

From: Capt. Edwin Galan, USPHS, Region VII, DHHS, Office of Minority Health

In the federal capacity that I hold, I offer these thoughts only as requested by some of you in a technical advisory, informational and neutral stance. I serve as the federal DHHS officer coordinating our Region VII states (Missouri, Iowa, Nebraska & Kansas) on public health care issues relevant to underrepresented populations via our Office of Minority Health. I have learned of your HB-2825 and desire to respectfully share neutral but highly informational remarks that you may desire to consider in discussing this bill.

As both an active primary care provider and health care administrator my personal experiences during 3 decades in the health care arena have offered great opportunity to witness first-hand the need for better organization and State level support for medical and health care interpretation across the entire U.S. but in particular for our Region VII states of which Kansas is a leader. The exponential growth of legal refugee and immigrant populations in Kansas demonstrates a need for many languages to be interpreted across the State for optimal health care.

Our federal stance of course on matters of improving the health care for people of Limited English Proficiency (LEP) is widely shared via the Presidential Executive Order #13166 of August 2000. Likewise supporting guidelines and mandates in this area are expounded via our U.S. Civil Rights enactions of Title VI. The federal Office of Civil Rights has vigorously pursued wide dissemination of information in this area and in Region VII they are also available to further share any direct information that your distinguished legislative body may need.

Personally, I have endeavored to work with the Kansas Department of Health and Environment (KDHE) and your recently conceived Office of Minority Health in this area by offering technical assistance and guidance as needed in this matter of qualified interpretation for medical and health care of LEP Kansans. We have found great interest in this public health matter and related health strategies on the part of the Hon. Secretary Bremby and his staff.

Of course, the optimal goal is for all Kansans to be English proficient as soon as possible, but in the meantime, for the greater objective of assuring safety and protection of LEP Kansans, your proposed HB 2825 may offer a strong "first-step" in rendering much needed structure and organization to the current health interpretation entities located throughout Kansas.

It is highly plausible that via such a House Bill, all Kansans (not just the LEP) may reap the added benefits of reduced medical error rates and costs for all providers, hospitals, etc., in Kansas. Sound evidenced based medical literature strongly supports the benefits of how using qualified medical interpreters can help in this manner but also with any

state Medicaid program (including Kansas') by shorter hospitalization rates and decreased costs, less diagnostic testing, less misdiagnosing and greater patient comprehension. This could positively impact the budget of Kansas health care dollars for every Kansan. It is widely understood that such measures can also help improve quality of care for all as well.

Some of the websites that support this are located at:
www.whitehouse.gov/omb/inforeg/lepfinal3-14.pdf for Federal Tips & Tools from the Field on LEP, dated 9/21/04
www.aafp.org/fpm for Amer. Academy of Family Physicians article of June 2004 "Getting the Most From Language Interpreters" by E. Herndon, MD and L. Joyce.
www.ncihc.org with a Sept 2005 publication on National Standards of Practice for Health Care Interpreters;
www.omhrc.gov/clas for the federally developed Culturally and Linguistically Appropriate Services (CLAS) national standards
www.lep.gov for federal Limited English Proficiency (LEP) guidelines and resources
www.healthlaw.org for the Nat'l Health Law Program with physician & hospital helps
www.NRHArural.org for the Nat'l Rural Health Assn, Winter 2004 Newsletter devoted to vast information sources applicable throughout all Kansas
www.healthtranslations.com for help with less common language interpretation needs
www.mhanet.com for the Missouri Hosp. Assn, who avidly supports interpreter use for all their member hospitals and is a neighbor state of KS... and the list goes on.

I ask you and your distinguished Senate colleagues to perhaps give consultation of our neighboring states in this area for other examples that might be of help in your decision making process for this HB 2825. Of course I too would be pleased to provide any other needed information in your deciding process for this bill. I can be contacted at my office at (816) 426-3295 or via my cell (816) 536-3518.

Thank you.

Sincerely,
Edwin M. Galan, MSN, MA, FNP-C
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Kansas Department of

Social and Rehabilitation Services

Gary Daniels, Secretary

For additional information contact:

Senate Public Health and Welfare Committee
March 16, 2006

Sub HB 2825 – Interpreter Data Bank and Qualifications

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Kansas Department of Social and Rehabilitation Services
Gary Daniels, Secretary

Senate Public Health and Welfare Committee
March 16, 2006

Sub HB 2825 – Interpreter Data Bank and Qualifications

Thank you for the opportunity to provide information about the Kansas Commission for the Deaf and Hard of Hearing (KCDHH) and its existing registry of sign language interpreters.

In accordance with KSA 75-5393, KCDHH maintains a registry of qualified sign language interpreters.

* The registry identifies whether interpreters are qualified in American Sign Language, transliteration, or Signed Exact English. The registry also identifies their certification level through the Kansas Quality Assurance Screening (KQAS) program or other national recognized certifications.
* Participation in the registry on the part of interpreters is currently voluntary. There is no fee to be listed, and KCDHH periodically undertakes activities to encourage participation and to keep the listing current.
* A total of 522 sign language interpreters are currently listed on the registry, with 280 of them having KQAS Certification Level 3 or higher. This certification level means they are qualified to work in any setting, including the health care arena.
* Individuals, organizations or agencies seeking an interpreter may contact KCDHH at 785-267-6100 or 800-432-0698 for statewide referral. Individuals may also contact one of six other private regional interpreter referral/coordinating agencies operating in Kansas. These agencies are listed on the KCDHH web site at: http://www.srskansas.org/kcdhh/text/coord_agencies.htm

SRS and KCDHH stand ready and willing to collaborate with the Kansas Department of Health and Environment to assure that customers, programs and facilities have access to this resource and to avoid duplication of this data bank function.

Thank you for the opportunity to present this written testimony.

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Kansas Commission on Disability Concerns

Testimony to Public Health and Welfare Committee
HCR 5011; A CONCURRENT RESOLUTION expressing the Legislature's recognition and appreciation for family caregivers throughout the state.
March 16, 2006

Chairperson Barnett and members of the committee, I am Kerrie Bacon, Legislative Liaison for the Kansas Commission on Disability Concerns (KCDC). We are charged with providing information to the Governor, the Legislature, and to State agencies about issues of concern to Kansans with disabilities (K.S.A. 74-6706).

The Kansas Commission on Disability Concerns urges you to support HCR 5011. Caregivers are a very important part of our society and this recognition is overdue and deserved.

The commission is supportive of this resolution with the proposed amendments and encourages you to recommend it favorably for passage to the full Senate.

Thank you for your time.

Senate Public Health & welfare Committee
Date: March 16, 2006
Attachment #2

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AARP Kansas

March 16, 2006
Senator Barnett, Chair
Public Health and Welfare Committee

Good afternoon Chairman Barnett and Members of the Senate Public Health and Welfare Committee. My name is Alyce Brown and I am the Southwest Regional Volunteer Coordinator for AARP. AARP Kansas represents the views of our more than 350,000 members in the state of Kansas. Thank you for this opportunity to express our support for HCR 5011 and caregivers of Kansas. Caregiving is a high priority issue for AARP Kansas.

Family caregivers refer to people who provide long-term care services and support to family members, friends, relatives and neighbors. Unpaid caregiver refers to people who provide care without pay.

In the 2004 AARP survey "Caregivers in the U.S., Spotlight on Kansas" it was estimated that approximately 446,000 adults in Kansas, 22 % of the total population, provide unpaid care to a relative or friend 18 or older.

These caregivers are a diverse group. Their caregiving experiences range from those that are relatively easy to those that are burdensome. We know that being a caregiver makes those who assume the heaviest responsibilities vulnerable to risk associated with poorer health, emotional stress and economic hardships.

As the baby boom generation ages over the next 25 years, the ranks of those needing care will swell and the numbers of those available to provide care will decrease. Future caregivers may feel even less choice about becoming caregiver or may provide care for two, three or more recipients. This will increase the caregiver burden.

AARP believes that unpaid caregivers deserve our attention and our assistance by:

- Helping current at-risk caregivers to continue to provide care to family without sacrificing their health, financial security and their quality of life.
- Expanding current caregiver programs to include all caregivers regardless of the age of care recipient.
- Encouraging families and states to begin to plan future needed services for the long-term care population.

As a step in recognizing the efforts of those who carry out the primary role of the unpaid caregiver, we respectfully request your support of HCR 5011 and Kansas caregivers. Thank you for your consideration in this matter.

Respectfully, Alyce Brown

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