

To: Must, Alan[Alan.Must@pharma.com]; Bennett, Pamela[Pamela.Bennett@pharma.com]; Samuel, Lally[Lally.Samuel@pharma.com]; Fisher, Windell[Windell.Fisher@pharma.com]
Cc: Sears, Terri[Terri.Sears@pharma.com]; Heins, James[James.Heins@pharma.com]
From: Barefoot, Linda
Sent: Mon 4/10/2006 11:06:07 AM
Subject: RE: pending California legislation

Alan,

You are absolutely right. One must read the entire proposed language of this bill to see exactly what the intent is. First, let me speak to the language that I believe the docs are concerned with and put it in its proper perspective. This is the section that deals with removing the exemption from disciplinary action for treating pain. At the three sessions of the California Pain Management Laws Task Force there was much discussion about this. The Deputy Attorney General, as well as other state attorneys, cited case after case where physicians were using this language as a shelter when they clearly were negligent in their care of their pain patients. They gave examples of physicians, both under prescribing and inappropriately prescribing, yet would cite this language as protection from any consequences of their actions or failure to act. The current laws governing the treatment of pain patients are very confusing to interpret in a court of law. The Task Force felt this was an opportunity with AB 2198 to clean up the laws and to cite specifically who a physician can and cannot treat for pain. Additionally, it has been unclear whether physicians could treat an "addict" for a painful condition and AB 2198 specifically addresses this and provides the conditions under which a physician **can** treat a pain patient for both maintenance of their drug addiction and for a painful condition (see text of bill).

I would refer anyone who has questions and concerns about the language of AB 2198 to Linda Whitney, Chief of Legislation, Medical Board of California. Linda is very open to receiving calls with questions about this proposed legislation and can help to put it into the proper intent and perspective. Her contact information is:

Office: 916-263-2389
Fax: 916-263-2387
Email: lwhitney@medbd.ca.gov

Please let me know if I can be of further help with this issue.

Regards,

Linda

*Linda Barefoot
Regional Director, State Government Affairs
Purdue Pharma, L.P.
Office: 303-664-9808
Fax: 303-664-9807
Email: linda.barefoot@pharma.com
Mobile: 303-641-0993*

From: Must, Alan
Sent: Monday, April 10, 2006 11:02 AM
To: Bennett, Pamela; Samuel, Lally; Barefoot, Linda; Fisher, Windell
Cc: Sears, Terri; Heins, James
Subject: RE: pending California legislation

PLAINTIFFS TRIAL
EXHIBIT

P-29984_00001

All,

Here is a copy of the proposed California legislation referred to in the email. The intent of the proposed bill is to clarify and expand the ability of healthcare professionals to provide treatment for pain. While it may appear that protections are being taken away, one must read the entire bill and put it into context. A group of pain advocates and pain physicians were involved in this exercise to replace and clarify existing legislation to the benefit of patients and physicians. Linda Barefoot participated on the task force and may be able to provide some additional information.

BILL NUMBER: AB 2198 AMENDED

BILL TEXT

AMENDED IN ASSEMBLY MARCH 28, 2006

INTRODUCED BY Assembly Member Houston

FEBRUARY 22, 2006

An act to amend Sections 725, 2241, ~~and 2242~~
2242, and 2242.1 of, and to repeal and add Section 2241.5
of, the Business and Professions Code, and to amend Section 11156 of
the Health and Safety Code, relating to healing arts.

LEGISLATIVE COUNSEL'S DIGEST

AB 2198, as amended, Houston Health care: controlled substances

and dangerous drugs.

Existing law makes it unprofessional conduct for specified health care providers to engage in repeated acts of clearly excessive prescribing or administering of drugs or treatment, unless the health care provider is a physician and surgeon in compliance with the California Intractable Pain Treatment Act.

This bill would delete the provision prohibiting disciplinary action against a physician and surgeon who is in compliance with the California Intractable Pain Treatment Act. The bill would define "clearly excessive" to mean an amount or extent that is without substantial medical basis and is substantially greater than the usual amount of prescribing, administering, or use of the therapeutic modalities.

Existing law, the Medical Practice Act, provides for the licensing and regulation of physicians and surgeons by the Medical Board of California, and the violation of specified provisions of the act is a crime. The California Intractable Pain Treatment Act, in the Medical Practice Act, authorizes a physician and surgeon to prescribe or administer controlled substances to a person in the course of treatment for a diagnosed condition causing intractable pain, except in certain circumstances, and prohibits disciplinary action against a physician and surgeon for such action.

This bill would define addict for purposes of these provisions. The bill would delete these provisions and would instead authorize a physician and surgeon to prescribe for, or dispense or administer to, a person for a medical condition drugs or prescription controlled

substances for the treatment of pain or a condition causing pain, including intractable pain. The bill would require the physician and surgeon to exercise reasonable care in determining whether a particular patient or condition, or complexity of the patient's treatment, including, but not limited to, a current or recent pattern of drug abuse, requires consultation with, or referral to, a more qualified specialist. A violation of this requirement would be a crime.

Existing law, except as specified, prohibits a person from prescribing or administering or dispensing a controlled substance to an addict or habitual user. Existing law generally makes it unprofessional conduct for a physician and surgeon to prescribe, sell, furnish, give away, or administer certain drugs to an addict or habitue, or to offer to do so, but contains certain exceptions from this provision.

This bill would delete the provision making it unprofessional conduct for a physician and surgeon to prescribe, sell, furnish, give away, or administer certain drugs to an addict or habitue, or to offer to do so ~~—, and would instead prohibit a physician and surgeon from prescribing, dispensing, or administering prescription drugs or controlled substances to an addict, except for purposes of maintenance on, or detoxification from, prescription drugs or controlled substances or in specified other instances—~~

. The bill would authorize a physician and surgeon to prescribe, dispense, or administer prescription drugs, including

prescription controlled substances, (1) to an addict under his or her treatment for a condition other than maintenance on, or detoxification from, prescription drugs or controlled substances and (2) under specified conditions to an addict for purposes of maintenance on, or detoxification from, prescription drugs or controlled substances. The bill would also authorize prescription drugs or controlled substances to be administered or applied by a physician and surgeon, or by a registered nurse acting under his or her instruction and supervision, in certain circumstances . A violation of this requirement would be a crime.

Existing law makes it unprofessional conduct for a physician and surgeon to prescribe, dispense, or furnish dangerous drugs without a good faith prior examination and medical indication . Existing law also, with specified exceptions, prohibits a person or entity from prescribing, dispensing, or furnishing, or causing to be prescribed, dispensed, or furnished, dangerous drugs or dangerous devices on the Internet for delivery to a person in California without a good faith prior examination and medical indication .

This bill would , for purposes of these provisions, require an appropriate prior examination instead of a good faith prior examination. The bill would make related legislative findings.

Because this bill would create new crimes, it would impose a state-mandated local program.

The California Constitution requires the state to reimburse local

agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes.
State-mandated local program: yes.

THE PEOPLE OF THE STATE OF CALIFORNIA DO ENACT AS FOLLOWS:

SECTION 1. The Legislature hereby finds and declares the following:

(a) The investigation and prosecution of pain management cases in California have evolved over the past 15 years.

(b) The Pain Patient's Bill of Rights and the Intractable Pain Treatment Act were created to ensure patients received adequate pain medication and to protect a physician and surgeon from being disciplined solely because of the amounts of controlled substances he or she prescribed or administered.

(c) California recognizes that prescription medication, including controlled substances, can play a critical role in the treatment of pain, and, in and of itself, is an insufficient basis to determine if a physician and surgeon has violated the standard of care in his or

her treatment of pain management patients.

(d) California also recognizes that the Intractable Pain Treatment Act may be an impediment to easily accessible pain treatment which can be confusing to both licensees and regulating entities. It can also provide a false sense of security to licensees who may erroneously believe it immunizes them from any actions against their license.

(e) In recognition of the Medical Board of California's consumer protection mandates, and in an attempt to provide better treatment of pain patients, as well as protect the public through the appropriate investigation and prosecution of those who violate the standard of care when treating pain patients, the Legislature recognizes that it is time to reflect upon the current state of pain management to aid both those who treat pain patients, as well as those who investigate and prosecute physicians and surgeons.

SEC. 2. Section 725 of the Business and Professions Code is amended to read:

725. (a) Repeated acts of clearly excessive prescribing, furnishing, dispensing, or administering of drugs or treatment, repeated acts of clearly excessive use of diagnostic procedures, or repeated acts of clearly excessive use of diagnostic or treatment facilities as determined by the standard of the community of licensees is unprofessional conduct for a physician and surgeon, dentist, podiatrist, psychologist, physical therapist, chiropractor, or optometrist.

(b) Any person who engages in repeated acts of clearly excessive

prescribing or administering of drugs or treatment is guilty of a misdemeanor and shall be punished by a fine of not less than one hundred dollars (\$100) nor more than six hundred dollars (\$600), or by imprisonment for a term of not less than 60 days nor more than 180 days, or by both the fine and imprisonment.

(c) For purposes of this section, "clearly excessive" shall mean an amount or extent that is both (1) without substantial medical basis and (2) substantially greater than the usual amount of prescribing, administration, or use of therapeutic modalities.

SEC. 3. Section 2241 of the Business and Professions Code is amended to read:

2241. (a) A physician and surgeon may ~~not~~ prescribe, dispense, or administer prescription drugs, including prescription controlled substances, to an addict under his or her treatment ~~—, except as follows:—~~ for a condition other than maintenance on, or detoxification from, prescription drugs or controlled substances.

~~—(1)—~~

(b) A physician and surgeon may only prescribe, dispense, or administer prescription drugs or prescription controlled substances to an addict for purposes of maintenance on or detoxification from prescription drugs or controlled substances as set forth in ~~Section 11217~~ subdivision (c) or in Sections 11215, 11217, 11217.5, 11218, 11219, and 11220 of the Health and Safety Code. Nothing in this ~~paragraph~~

subdivision shall authorize a physician and surgeon to prescribe, dispense, or administer dangerous drugs or controlled substances to a person he or she knows or reasonably believes is using or will use the drugs or substances for a nonmedical purpose.

~~—(2) Drugs or controlled substances may be administered or applied to an addict—~~

(c) *Notwithstanding subdivision (a), prescription drugs or controlled substances may also be administered or applied by a physician and surgeon, or by a registered nurse acting under his or her instruction and supervision, under the following circumstances:*

~~—(A)—~~

(1) Emergency treatment of a patient whose addiction is complicated by the presence of incurable disease, acute accident, illness, or injury, or the infirmities attendant upon age.

~~—(B)—~~

(2) Treatment of addicts in state licensed institutions where the patient is kept under restraint and control, or in city or county jails or state prisons.

~~—(C)—~~

(3) Treatment of addicts as provided for by Section 11217.5 of the Health and Safety Code.

~~—(b)—~~

(d) For purposes of this section and Section 2241.5, "addict" means a person whose actions are characterized by one or

more of the following:

- (1) Impaired control over drug use.
- (2) Compulsive use.
- (3) Continued use despite harm and craving.

SEC. 4. Section 2241.5 of the Business and Professions Code is repealed.

SEC. 5. Section 2241.5 is added to the Business and Professions Code, to read:

2241.5. (a) A physician and surgeon may prescribe for , or dispense or administer to , a person under his or her treatment for a medical condition dangerous drugs or prescription controlled substances for the treatment of pain or a condition causing pain, including, but not limited to, intractable pain.

(b) A physician and surgeon's authority under this section shall be subject to the provisions of Sections 725, 2234, 2241, 2242, and 2242.1, and Sections 11152, 11153, and 11154 of the Health and Safety Code. Nothing in this section shall authorize a physician and surgeon to prescribe, administer or dispense dangerous drugs or controlled substances to a person he or she knows or reasonably believes is using or will use the drugs or substances for a non-medical purpose.

(c) Any physician and surgeon has the legal authority to treat a patient for pain using dangerous drugs or prescription controlled substances but the prescribing, administering, or dispensing

physician and surgeon shall exercise reasonable care in determining whether a particular patient or condition, or complexity of the patient's treatment, including, but not limited to, a current or recent pattern of drug abuse, requires consultation with or referral to a more qualified specialist.

SEC. 6. Section 2242 of the Business and Professions Code is amended to read:

2242. (a) Prescribing, dispensing, or furnishing dangerous drugs as defined in Section 4022 without an appropriate prior examination and a medical indication, constitutes unprofessional conduct.

(b) No licensee shall be found to have committed unprofessional conduct within the meaning of this section if, at the time the drugs were prescribed, dispensed, or furnished, any of the following applies:

(1) The licensee was a designated physician and surgeon or podiatrist serving in the absence of the patient's physician and surgeon or podiatrist, as the case may be, and if the drugs were prescribed, dispensed, or furnished only as necessary to maintain the patient until the return of his or her practitioner, but in any case no longer than 72 hours.

(2) The licensee transmitted the order for the drugs to a registered nurse or to a licensed vocational nurse in an inpatient facility, and if both of the following conditions exist:

(A) The practitioner had consulted with the registered nurse or licensed vocational nurse who had reviewed the patient's records.

(B) The practitioner was designated as the practitioner to serve

in the absence of the patient's physician and surgeon or podiatrist, as the case may be.

(3) The licensee was a designated practitioner serving in the absence of the patient's physician and surgeon or podiatrist, as the case may be, and was in possession of or had utilized the patient's records and ordered the renewal of a medically indicated prescription for an amount not exceeding the original prescription in strength or amount or for more than one refilling.

(4) The licensee was acting in accordance with Section 120582 of the Health and Safety Code.

SEC. 7. Section 2242.1 of the Business and Professions Code is amended to read:

2242.1. (a) No person or entity may prescribe, dispense, or furnish, or cause to be prescribed, dispensed, or furnished, dangerous drugs or dangerous devices, as defined in Section 4022, on the Internet for delivery to any person in this state, without ~~a good faith~~ an appropriate prior examination and medical indication ~~therefor~~ , except as authorized by Section 2242.

(b) Notwithstanding any other provision of law, a violation of this section may subject the person or entity that has committed the violation to either a fine of up to twenty-five thousand dollars (\$25,000) per occurrence pursuant to a citation issued by the board or a civil penalty of twenty-five thousand dollars (\$25,000) per occurrence.

(c) The Attorney General may bring an action to enforce this section and to collect the fines or civil penalties authorized by subdivision (b).

(d) For notifications made on and after January 1, 2002, the Franchise Tax Board, upon notification by the Attorney General or the board of a final judgment in an action brought under this section, shall subtract the amount of the fine or awarded civil penalties from any tax refunds or lottery winnings due to the person who is a defendant in the action using the offset authority under Section 12419.5 of the Government Code, as delegated by the Controller, and the processes as established by the Franchise Tax Board for this purpose. That amount shall be forwarded to the board for deposit in the Contingent Fund of the Medical Board of California.

(e) If the person or entity that is the subject of an action brought pursuant to this section is not a resident of this state, a violation of this section shall, if applicable, be reported to the person's or entity's appropriate professional licensing authority.

(f) Nothing in this section shall prohibit the board from commencing a disciplinary action against a physician and surgeon pursuant to Section 2242.

~~SEC. 7.~~ SEC. 8. Section 11156 of the Health and Safety Code is amended to read:

11156. (a) No person shall prescribe for or administer, or dispense a controlled substance to an addict ~~or habitual user~~, or to any person representing himself or herself as such, except as permitted by this division.

(b) For purposes of this section, "addict" means a person whose actions are characterized by one or more of the following:

- (1) Impaired control over drug use.
- (2) Compulsive use.
- (3) Continued use despite harm and craving.

~~SEC. 8.~~ SEC. 9. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

Alan H. Must
Vice President
State Government and Legislative Affairs
Purdue Pharma L.P.
One Stamford Forum
201 Tresser Blvd.
Stamford, CT 06901-3431
T: (203) 588-8121
F: (203) 588-6033
E: alan.must@pharma.com

From: Bennett, Pamela
Sent: Monday, April 10, 2006 10:28 AM
To: Samuel, Lally; Must, Alan; Barefoot, Linda; Fisher, Windell
Cc: Sears, Terri; Heins, James
Subject: RE: pending California legislation
Importance: High

Lally-

I will defer to Linda and Alan about the accuracy and specifics of the legislation...and how we should respond. It is interesting that physicians are expressing these concerns to their patients.

If it makes sense, you can refer her to me and I could refer her to a variety of organizations who may be interested in becoming engaged such as the CA AAFP chapter, California Pain initiative (if Malibu is by LA to the Southern California branch if near San Francisco to the Northern California branch), National Fibromyalgia Association, California ASPMN chapter, and AAPManagement. If we go down this road, I can provide you with the contact information for individuals that should be contacted within the specific organizations. She may also wish to express her concerns to the local media.

Windell-

I thought you would want your rep to know about the concerns of the MD below.

Kindest regards-

Pamela

From: Samuel, Lally
Sent: Monday, April 10, 2006 10:10 AM
To: Must, Alan; Bennett, Pamela
Subject: FW: pending California legislation

This email was sent to PAP mailbox. I am not familiar with this legislation. Please advise as to how to respond to this consumer.

Thanks,
Lally

From: Melody Beattie [mailto:melodylbeattie@msn.com]
Sent: Saturday, April 08, 2006 4:36 PM
To: Partners Against Pain
Subject: pending California legislation

I am writing to make you aware of pending California legislation (Bill AB 2198). This bill will be next voted on, on April 17. If it is passed, it will remove the portion of California's intractable pain act that provides protection to prescribing physicians. This means that all pain doctors will instantly close their doors on April 17. My doctor, Dr. Forest Tennant, advised me yesterday that his clinic will close immediately -- as will all other pain clinics prescribing medications in the state of California.

I am imploring, begging you to intervene and advocate on our behalf, on behalf of the doctors and physicians in the State of California who need medication and who need compassionate, informed doctors. Please let me know if there is anything you can do or are willing to do for us.

Thank you,
Melody Beattie

310-317-4301
25338 Malibu Rd, #2
Malibu, California 90265