Attachment 12

AMENDED IN SENATE JUNE 23, 2005

AMENDED IN SENATE JUNE 6, 2005

AMENDED IN ASSEMBLY MARCH 29, 2005

CALIFORNIA LEGISLATURE—2005–06 REGULAR SESSION

ASSEMBLY BILL No. 522

Introduced by Assembly Members Plescia and Bogh
(Coauthors: Assembly Members Spitzer and Vargas)

February 16, 2005

An act to amend Section 1261.6 of the Health and Safety Code, ~~to amend Sections 290 and 290.46 of, and~~ to add Section 290.02 to, the Penal Code, and to add Section 14133.225 to the Welfare and Institutions Code, relating to prescription drugs and other therapies, and declaring the urgency thereof, to take effect immediately.

LEGISLATIVE COUNSEL'S DIGEST

AB 522, as amended, Plescia. Automated drug delivery system: Medi-Cal coverage: drugs or other therapies: registered sex offenders.

Existing law provides for skilled nursing and intermediate care facilities to use an automated drug delivery system to store and distribute drugs, and to track the movement of drugs into and out of the system. Existing law regulates the manner in which a pharmacist stocks and oversees the removal of drugs from an automated drug delivery system.

This bill would clarify existing law to define pharmacy services and to require a pharmacist reviewing an order for a drug to check for contraindications and adverse drug reactions. This bill would further clarify existing law to prevent licensed personnel from accessing a different drug or dose of a drug than that approved by a pharmacist.

Existing law provides for the Medi-Cal program, which is administered by the State Department of Health Services and under which qualified low-income persons receive health care services, pursuant to a schedule of health care benefits. The Med-Cal program is, in part, governed and funded by federal Medicaid provisions.

Existing law requires a person who has committed one or more designated sex crimes to register with the law enforcement agency of the city, county, city and county, or campus in which the person resides. Existing law provides that the Department of Justice shall make available information concerning specified registered sex offenders to the public via an Internet Web site.

This bill would provide that the State Department of Health Services shall not provide or pay for any prescription drug or therapy to treat erectile dysfunction for any Medi-Cal recipient required to register pursuant to these provisions, except to the extent it is required under federal law.

This bill would require the Department of Justice to ~~make available sex offender identification information concerning~~ *provide, upon written request, the names and relevant information pertaining to* persons required to register under these provisions to any state governmental entity responsible for authorizing or providing publicly funded prescription drugs or other therapies to treat erectile dysfunction of these persons.

This bill would authorize the Department of Justice to establish a fee for the above requests.

This bill would declare that it is to take effect immediately as an urgency statute.

Vote: ⅔. Appropriation: no. Fiscal committee: yes. State-mandated local program: no.

The people of the State of California do enact as follows:

1 SECTION 1. Section 1261.6 of the Health and Safety Code is
2 amended to read:
3 1261.6. (a) (1) For purposes of this section and Section
4 1261.5, an "automated drug delivery system" means a
5 mechanical system that performs operations or activities, other
6 than compounding or administration, relative to the storage,
7 dispensing, or distribution of drugs. An automated drug delivery
8 system shall collect, control, and maintain all transaction

information to accurately track the movement of drugs into and out of the system for security, accuracy, and accountability.

(2) For purposes of this section, "facility" means a health facility licensed pursuant to subdivision (c), (d), or both, of Section 1250 that has an automated drug delivery system provided by a pharmacy.

(3) For purposes of this section, "pharmacy services" means the provision of both routine and emergency drugs and biologicals to meet the needs of the patient as prescribed by a physician.

(b) Transaction information shall be made readily available in a written format for review and inspection by individuals authorized by law. These records shall be maintained in the facility for a minimum of three years.

(c) Individualized and specific access to automated drug delivery systems shall be limited to facility and contract personnel authorized by law to administer drugs.

(d) (1) The facility and the pharmacy shall develop and implement written policies and procedures to ensure safety, accuracy, accountability, security, patient confidentiality, and maintenance of the quality, potency, and purity of stored drugs. Policies and procedures shall define access to the automated drug delivery system and limits to access to equipment and drugs.

(2) All policies and procedures shall be maintained at the pharmacy operating the automated drug delivery system and the location where the automated drug delivery system is being used.

(e) When used as an emergency pharmaceutical supplies container, drugs removed from the automated drug delivery system shall be limited to the following:

(1) A new drug order given by a prescriber for a patient of the facility for administration prior to the next scheduled delivery from the pharmacy, or 72 hours, whichever is less. The drugs shall be retrieved only upon authorization by a pharmacist and after the pharmacist has reviewed the prescriber's order and the patient's profile for potential contraindications and adverse drug reactions.

(2) Drugs that a prescriber has ordered for a patient on an as-needed basis, if the utilization and retrieval of those drugs are subject to ongoing review by a pharmacist.

(3) Drugs designed by the patient care policy committee or pharmaceutical service committee of the facility as emergency drugs or acute onset drugs. These drugs may be retrieved from an automated drug delivery system pursuant to the order of a prescriber for emergency or immediate administration to a patient of the facility. Within 48 hours after retrieval under this paragraph, the case shall be reviewed by a pharmacist.

(f) When used to provide pharmacy services pursuant to Section 4119.1 of the Business and Professions Code, the automated drug delivery system shall be subject to all of the following requirements:

(1) Drugs removed from the automated drug delivery system for administration to a patient shall be in properly labeled units of administration containers or packages.

(2) A pharmacist shall review and approve all orders prior to a drug being removed from the automated drug delivery system for administration to a patient. The pharmacist shall review the prescriber's order and the patient's profile for potential contraindications and adverse drug reactions.

(3) The pharmacy providing services to the facility pursuant to Section 4119.1 of the Business and Professions Code shall control access to the drugs stored in the automated drug delivery system.

(4) Access to the automated drug delivery system shall be controlled and tracked using an identification or password system or biosensor.

(5) The automated drug delivery system shall make a complete and accurate record of all transactions which will include all users accessing the system and all drugs added to or removed from the system.

(6) After the pharmacist reviews the prescriber's order, access by licensed personnel to the automated drug delivery system shall be limited only to the drug as ordered by the prescriber and reviewed by the pharmacist and that is specific to the patient. When the prescriber's order requires a dosage variation of the same drug, licensed personnel shall only have access to the drug ordered for that scheduled time of administration.

(g) The stocking of an automated drug delivery system shall be performed by a pharmacist. If the automated drug delivery system utilizes removable pockets or drawers, or similar

technology, the stocking system may be done outside of the facility and be delivered to the facility if all of the following conditions are met:

(1) The task of placing drugs into the removable pockets or drawers is performed by a pharmacist or by an intern pharmacist or a pharmacy technician working under the direct supervision of a pharmacist.

(2) The removable pockets or drawers are transported between the pharmacy and the facility in a secure tamper-evident container.

(3) The facility, in conjunction with the pharmacy, has developed policies and procedures to ensure that the pockets or drawers are properly placed into the automated drug delivery system.

(h) Review of the drugs contained within, and the operation and maintenance of, the automated drug delivery system shall be done in accordance with law and shall be the responsibility of the pharmacy. The review shall be conducted on a monthly basis by a pharmacist and shall include a physical inspection of the drugs in the automated drug delivery system, an inspection of the automated drug delivery system machine for cleanliness, and a review of all transaction records in order to verify the security and accountability of the system.

(i) Drugs dispensed from an automated drug delivery system that meets the requirements of this section shall not be subject to the labeling requirements of Section 4076 of the Business and Professions Code or Section 111480 of this code if the drugs to be placed into the automated drug delivery system are in unit dose packaging or unit of use and if the information required by Section 4076 of the Business and Professions Code and Section 111480 of this code is readily available at the time of drug administration.

~~SEC. 2. Section 290 of the Penal Code is amended to read:~~

~~290. (a) (1) (A) Every person described in paragraph (2), for the rest of his or her life while residing in California, or while attending school or working in California, as described in subparagraph (G), shall be required to register with the chief of police of the city in which he or she is residing, or the sheriff of the county if he or she is residing is located, in an unincorporated area or city that has no police department, and, additionally, with~~

~~the chief of police of a campus of the University of California, the California State University, or community college if he or she is residing upon the campus or in any of its facilities, within five working days of coming into, or changing his or her residence within, any city, county, or city and county, or campus in which he or she temporarily resides.~~

~~(B) If the person who is registering has more than one residence address at which he or she regularly resides, he or she shall register in accordance with subparagraph (A) in each of the jurisdictions in which he or she regularly resides, regardless of the number of nights spent there. If all of the addresses are within the same jurisdiction, the person shall provide the registering authority with all of the addresses where he or she regularly resides.~~

~~(C) Every person described in paragraph (2), for the rest of his or her life while living as a transient in California shall be required to register, as follows:~~

~~(i) A transient must register, or reregister if the person has previously registered, within five working days from release from incarceration, placement or commitment, or release on probation, pursuant to paragraph (1) of subdivision (a), except that if the person previously registered at a transient less than 30 days from the date of his or her release from incarceration, he or she does not need to reregister as a transient until his or her next required 30-day update of registration. If a transient is not physically present in any one jurisdiction for five consecutive working days, he or she must register in the jurisdiction in which he or she is physically present on the fifth working day following release, pursuant to paragraph (1) of subdivision (a). Beginning on or before the 30th day following initial registration upon release, a transient must reregister no less than once every 30 days thereafter. A transient shall register with the chief of police of the city in which he or she is physically present within that 30-day period, or the sheriff of the county if he or she is physically present in an unincorporated area or city that has no police department, and additionally, with the chief of police of a campus of the University of California, the California State University, or community college if he or she is physically present upon the campus or in any of its facilities. A transient must reregister no less than once every 30 days regardless of the~~

~~length of time he or she has been physically present in the particular jurisdiction in which he or she reregisters. If a transient fails to reregister within any 30-day period, he or she may be prosecuted in any jurisdiction in which he or she is physically present.~~

~~(ii) A transient who moves to a residence shall have five working days within which to register at that address, in accordance with subparagraph (A) of paragraph (1) of subdivision (a). A person registered at a residence address in accordance with subparagraph (A) of paragraph (1) of subdivision (a), who becomes transient shall have five working days within which to reregister as a transient in accordance with clause (i).~~

~~(iii) Beginning or his or her first birthday following registration, a transient shall register annually, within five working days of his or her birthday, to update his or her registration with the entities described in clause (i). A transient shall register in whichever jurisdiction he or she is physically present on that date. At the 30-day updates and the annual update, a transient shall provide current information as required on the Department of Justice annual update form, including the information described in subparagraphs (A) to (C), inclusive, of paragraph (2) of subdivision (c), and the information specified in clause (iv).~~

~~(iv) A transient shall, upon registration and reregistration, provide current information as required on the Department of Justice registration forms, and shall also list the places where he or she sleeps, eats, works, frequents, and engages in leisure activities. If a transient changes or adds to the places listed on the form during the 30-day period, he or she does not need to report the new place or places until the next required reregistration.~~

~~(v) Failure to comply with the requirement of reregistering every 30 days following initial registration pursuant to clause (i) of this subparagraph shall be punished in accordance with paragraph (6) of subdivision (g). Failure to comply with any other requirement of this section shall be punished in accordance with either paragraph (1) or (2) of subdivision (g).~~

~~(vi) A transient who moves out of state shall inform, in person or in writing, the chief of police in the city in which he or she is physically present, or the sheriff of the county, if he or she~~

~~physically present in an unincorporated area or city that has no police department, within five working days of his or her move out of state. The transient shall inform that registering agency of his or her planned destination, residence or transient location out of state, and any plans he or she has to return to California, if known. The law enforcement agency shall, within three days after receipt of this information, forward a copy of the change of location information to the Department of Justice. The department shall forward appropriate registration data to the law enforcement agency having local jurisdiction of the new place of residence or location.~~

~~(vii) For purposes of this section, "transient" means a person who has no residence. "Residence" means a place where a person is living or temporarily staying for more than five days, such as a shelter or structure that can be located by a street address, including, but not limited to, houses, apartment buildings, motels, hotels, homeless shelters, and recreational and other vehicles.~~

~~(viii) The transient registrant's duty to update his or her registration no less than every 30 days shall begin with his or her second transient update following the date this subdivision became effective.~~

~~(D) Beginning on his or her first birthday following registration or change of address, the person shall be required to register annually, within five working days of his or her birthday, to update his or her registration with the entities described in subparagraph (A). At the annual update, the person shall provide current information as required on the Department of Justice annual update form, including the information described in subparagraphs (A) to (C), inclusive, of paragraph (2) of subdivision (e).~~

~~(E) In addition, every person who has ever been adjudicated a sexually violent predator, as defined in Section 6600 of the Welfare and Institutions Code, shall, after his or her release from custody, verify his or her address no less than once every 90 days and place of employment, including the name and address of the employer, in a manner established by the Department of Justice.~~

~~(F) No entity shall require a person to pay a fee to register or update his or her registration pursuant to this section. The registering agency shall submit registrations, including annual~~

~~updates or changes of address, directly into the Department of Justice Violent Crime Information Network (VCIN).~~

~~(G) Persons required to register in their state of residence who are out-of-state residents employed, or carrying on a vocation in California on a full-time or part-time basis, with or without compensation, for more than 14 days, or for an aggregate period exceeding 30 days in a calendar year, shall register in accordance with subparagraph (A). Persons described in paragraph (2) who are out-of-state residents enrolled in any educational institution in California, as defined in Section 22129 of the Education Code, on a full-time or part-time basis, shall register in accordance with subparagraph (A). The place where the out-of-state resident is located, for purposes of registration, shall be the place where the person is employed, carrying on a vocation, or attending school. The out-of-state resident subject to this subparagraph shall, in addition to the information required pursuant to subdivision (e), provide the registering authority with the name of his or her place of employment or the name of the school attended in California, and his or her address or location in his or her state of residence. The registration requirement for persons subject to this subparagraph shall become operative on November 25, 2000. The terms "employed or carries on a vocation" include employment whether or not financially compensated, volunteered, or performed for government or educational benefit.~~

~~(2) The following persons shall be required to register pursuant to paragraph (1):~~

~~(A) Any person who, since July 1, 1944, has been or is hereafter convicted in any court in this state or in any federal or military court of a violation of Section 207 or 209 committed with intent to violate Section 261, 286, 288, 288a, or 289, Section 220, except assault to commit mayhem, Section 243.4, paragraph (1), (2), (3), (4), or (6) of subdivision (a) of Section 261, or paragraph (1) of subdivision (a) of Section 262 involving the use of force or violence for which the person is sentenced to the state prison, Section 264.1, 266, or 266c, subdivision (b) of Section 266h, subdivision (b) of Section 266i, Section 266j, 267, 269, 285, 286, 288, 288a, 288.5, or 289, Section 311.1, subdivision (b), (c), or (d) of Section 311.2, Section 311.3, 311.4, 311.10, 311.11, or 647.6, former Section 647a, subdivision (c) of Section 653f, subdivision 1 or 2 of Section 314, any offense**

~~involving lewd or lascivious conduct under Section 272, or any felony violation of Section 288.2; or any statutory predecessor that includes all elements of one of the above-mentioned offenses; or any person who since that date has been or is hereafter convicted of the attempt to commit any of the above-mentioned offenses.~~

~~(B) Any person who, since July 1, 1944, has been or hereafter is released, discharged, or paroled from a penal institution where he or she was confined because of the commission or attempted commission of one of the offenses described in subparagraph (A).~~

~~(C) Any person who, since July 1, 1944, has been or hereafter is determined to be a mentally disordered sex offender under Article 1 (commencing with Section 6300) of Chapter 2 of Part 2 of Division 6 of the Welfare and Institutions Code or any person who has been found guilty in the guilt phase of a trial for an offense for which registration is required by this section but who has been found not guilty by reason of insanity in the sanity phase of the trial.~~

~~(D) (i) Any person who, since July 1, 1944, has been, or is hereafter convicted in any other court, including any state, federal, or military court, of any offense that, if committed or attempted in this state, would have been punishable as one or more of the offenses described in subparagraph (A).~~

~~(ii) Any person ordered by any other court, including any state, federal, or military court, to register as a sex offender for any offense, if the court found at the time of conviction or sentencing that the person committed the offense as a result of sexual compulsion or for purposes of sexual gratification.~~

~~(iii) Except as provided in clause (iv), any person who would be required to register while residing in the state of conviction for a sex offense committed in that state.~~

~~(iv) Clause (iii) shall not apply to a person required to register in the state of conviction if the conviction was for the equivalent of one of the following offenses, and the person is not subject to clause (i):~~

~~(I) Indecent exposure, pursuant to Section 314.~~

~~(II) Unlawful sexual intercourse, pursuant to Section 261.5.~~

~~(III) Incest, pursuant to Section 285.~~

~~(IV) Sodomy, pursuant to Section 286, or oral copulation, pursuant to Section 288a, provided that the offender notifies the Department of Justice that the sodomy or oral copulation conviction was for conduct between consenting adults, as described in subparagraph (F) of paragraph (2) of subdivision (a), and the department is able, upon the exercise of reasonable diligence, to verify that fact.~~

~~(E) Any person ordered by any court to register pursuant to this section for any offense not included specifically in this section if the court finds at the time of conviction or sentencing that the person committed the offense as a result of sexual compulsion or for purposes of sexual gratification. The court shall state on the record the reasons for its findings and the reasons for requiring registration.~~

~~(F) (i) Notwithstanding any other subdivision, a person who was convicted before January 1, 1976, under subdivision (a) of Section 286, or Section 288a, shall not be required to register pursuant to this section for that conviction if the conviction was for conduct between consenting adults that was decriminalized by Chapter 71 of the Statutes of 1975 or Chapter 1139 of the Statutes of 1976. The Department of Justice shall remove that person from the Sex Offender Registry, and the person is discharged from his or her duty to register pursuant to the following procedure:~~

~~(I) The person submits to the Department of Justice official documentary evidence, including court records or police reports, that demonstrate that the person's conviction pursuant to either of those sections was for conduct between consenting adults that was decriminalized; or~~

~~(II) The person submits to the department a declaration stating that the person's conviction pursuant to either of those sections was for consensual conduct between adults that has been decriminalized. The declaration shall be confidential and not a public record, and shall include the person's name, address, telephone number, date of birth, and a summary of the circumstances leading to the conviction, including the date of the conviction and county of the occurrence.~~

~~(III) The department shall determine whether the person's conviction was for conduct between consensual adults that has been decriminalized. If the conviction was for consensual~~

~~conduct between adults that has been decriminalized, and the person has no other offenses for which he or she is required to register pursuant to this section, the department shall, within 60 days of receipt of those documents, notify the person that he or she is relieved of the duty to register, and shall notify the local law enforcement agency with which the person is registered that he or she has been relieved of the duty to register. The local law enforcement agency shall remove the person's registration from its files within 30 days of receipt of notification. If the documentary or other evidence submitted is insufficient to establish the person's claim, the department shall, within 60 days of receipt of those documents, notify the person that his or her claim cannot be established, and that the person shall continue to register pursuant to this section. The department shall provide, upon the person's request, any information relied upon by the department in making its determination that the person shall continue to register pursuant to this section. Any person whose claim has been denied by the department pursuant to this clause may petition the court to appeal the department's denial of the person's claim.~~

~~(ii) On or before July 1, 1998, the department shall make a report to the Legislature concerning the status of persons who may come under the provisions of this subparagraph, including the number of persons who were convicted before January 1, 1976, under subdivision (a) of Section 286 or Section 288a and are required to register under this section, the average age of these persons, the number of these persons who have any subsequent convictions for a registerable sex offense, and the number of these persons who have sought successfully or unsuccessfully to be relieved of their duty to register under this section.~~

~~(b) (1) Any person who is released, discharged, or paroled from a jail, state or federal prison, school, road camp, or other institution where he or she was confined because of the commission or attempted commission of one of the offenses specified in subdivision (a) or is released from a state hospital to which he or she was committed as a mentally disordered sex offender under Article 1 (commencing with Section 6300) of Chapter 2 of Part 2 of Division 6 of the Welfare and Institutions Code, shall, prior to discharge, parole, or release, be informed of~~

~~his or her duty to register under this section by the official in charge of the place of confinement or hospital, and the official shall require the person to read and sign any form that may be required by the Department of Justice, stating that the duty of the person to register under this section has been explained to the person. The official in charge of the place of confinement or hospital shall obtain the address where the person expects to reside upon his or her discharge, parole, or release and shall report the address to the Department of Justice. The official shall at the same time forward a current photograph of the person to the Department of Justice.~~

~~(2) The official in charge of the place of confinement or hospital shall give one copy of the form to the person and shall send one copy to the Department of Justice and one copy to the appropriate law enforcement agency or agencies having jurisdiction over the place the person expects to reside upon discharge, parole, or release. If the conviction that makes the person subject to this section is a felony conviction, the official in charge shall, not later than 45 days prior to the scheduled release of the person, send one copy to the appropriate law enforcement agency or agencies having local jurisdiction where the person expects to reside upon discharge, parole, or release; one copy to the prosecuting agency that prosecuted the person; and one copy to the Department of Justice. The official in charge of the place of confinement or hospital shall retain one copy.~~

~~(c) (1) Any person who is convicted in this state of the commission or attempted commission of any of the offenses specified in subdivision (a) and who is released on probation, shall, prior to release or discharge, be informed of the duty to register under this section by the probation department, and a probation officer shall require the person to read and sign any form that may be required by the Department of Justice, stating that the duty of the person to register under this section has been explained to him or her. The probation officer shall obtain the address where the person expects to reside upon release or discharge and shall report within three days the address to the Department of Justice. The probation officer shall give one copy of the form to the person, send one copy to the Department of Justice, and forward one copy to the appropriate law enforcement~~

~~agency or agencies having local jurisdiction where the person expects to reside upon his or her discharge, parole, or release.~~

~~(2) Any person who is convicted in this state of the commission or attempted commission of any of the offenses specified in subdivision (a) and who is granted conditional release without supervised probation, or discharged upon payment of a fine, shall, prior to release or discharge, be informed of the duty to register under this section in open court by the court in which the person has been convicted, and the court shall require the person to read and sign any form that may be required by the Department of Justice, stating that the duty of the person to register under this section has been explained to him or her. If the court finds that it is in the interest of the efficiency of the court, the court may assign the bailiff to require the person to read and sign forms under this section. The court shall obtain the address where the person expects to reside upon release or discharge and shall report within three days the address to the Department of Justice. The court shall give one copy of the form to the person, send one copy to the Department of Justice, and forward one copy to the appropriate law enforcement agency or agencies having local jurisdiction where the person expects to reside upon his or her discharge, parole, or release.~~

~~(d) (1) Any person who, on or after January 1, 1986, is discharged or paroled from the Department of the Youth Authority to the custody of which he or she was committed after having been adjudicated a ward of the juvenile court pursuant to Section 602 of the Welfare and Institutions Code because of the commission or attempted commission of any offense described in paragraph (3) shall be subject to registration under the procedures of this section.~~

~~(2) Any person who is discharged or paroled from a facility in another state that is equivalent to the Department of the Youth Authority, to the custody of which he or she was committed because of an offense which, if committed or attempted in this state, would have been punishable as one or more of the offenses described in paragraph (3), shall be subject to registration under the procedures of this section.~~

~~(3) Any person described in this subdivision who committed an offense in violation of any of the following provisions shall be required to register pursuant to this section:~~

~~(A) Assault with intent to commit rape, sodomy, oral copulation, or any violation of Section 264.1, 288, or 289 under Section 220.~~

~~(B) Any offense defined in paragraph (1), (2), (3), (4), or (6) of subdivision (a) of Section 261, Section 264.1, 266c, or 267, paragraph (1) of subdivision (b) of, or subdivision (c) or (d) of, Section 286, Section 288 or 288.5, paragraph (1) of subdivision (b) of, or subdivision (c) or (d) of, Section 288a, subdivision (a) of Section 289, or Section 647.6.~~

~~(C) A violation of Section 207 or 209 committed with the intent to violate Section 261, 286, 288, 288a, or 289.~~

~~(4) Prior to discharge or parole from the Department of the Youth Authority, any person who is subject to registration under this subdivision shall be informed of the duty to register under the procedures set forth in this section. Department of the Youth Authority officials shall transmit the required forms and information to the Department of Justice.~~

~~(5) All records specifically relating to the registration in the custody of the Department of Justice, law enforcement agencies, and other agencies or public officials shall be destroyed when the person who is required to register has his or her records sealed under the procedures set forth in Section 781 of the Welfare and Institutions Code. This subdivision shall not be construed as requiring the destruction of other criminal offender or juvenile records relating to the case that are maintained by the Department of Justice, law enforcement agencies, the juvenile court, or other agencies and public officials unless ordered by a court under Section 781 of the Welfare and Institutions Code.~~

~~(c) (1) On or after January 1, 1998, upon incarceration, placement, or commitment, or prior to release on probation, any person who is required to register under this section shall preregister. The preregistering official shall be the admitting officer at the place of incarceration, placement, or commitment, or the probation officer if the person is to be released on probation. The preregistration shall consist of all of the following:~~

~~(A) A preregistration statement in writing, signed by the person, giving information that shall be required by the Department of Justice.~~

~~(B) The fingerprints and a current photograph of the person.~~

~~(C) Any person who is preregistered pursuant to this subdivision is required to be preregistered only once.~~

~~(2) A person described in paragraph (2) of subdivision (a) shall register, or reregister if the person has previously registered, upon release from incarceration, placement, commitment, or release on probation pursuant to paragraph (1) of subdivision (a). The registration shall consist of all of the following:~~

~~(A) A statement in writing signed by the person, giving information as shall be required by the Department of Justice and giving the name and address of the person's employer, and the address of the person's place of employment if that is different from the employer's main address.~~

~~(B) The fingerprints and a current photograph of the person taken by the registering official.~~

~~(C) The license plate number of any vehicle owned by, regularly driven by, or registered in the name of the person.~~

~~(D) Notice to the person that, in addition to the requirements of paragraph (4), he or she may have a duty to register in any other state where he or she may relocate.~~

~~(E) Copies of adequate proof of residence, which shall be limited to a California driver's license, California identification card, recent rent or utility receipt, printed personalized checks or other recent banking documents showing that person's name and address, or any other information that the registering official believes is reliable. If the person has no residence and no reasonable expectation of obtaining a residence in the foreseeable future, the person shall so advise the registering official and shall sign a statement provided by the registering official stating that fact. Upon presentation of proof of residence to the registering official or a signed statement that the person has no residence, the person shall be allowed to register. If the person claims that he or she has a residence but does not have any proof of residence, he or she shall be allowed to register but shall furnish proof of residence within 30 days of the date he or she is allowed to register.~~

~~(3) Within three days thereafter, the preregistering official or the registering law enforcement agency or agencies shall forward the statement, fingerprints, photograph, and vehicle license plate number, if any, to the Department of Justice.~~

~~(f) (1) If any person who is required to register pursuant to this section and who has a residence address changes his or her residence address, whether within the jurisdiction in which he or she is currently registered or to a new jurisdiction inside or outside the state, the person shall inform, in writing within five working days, the law enforcement agency or agencies with which he or she last registered of the new address or transient location and any plans he or she has to return to California, if known. If the person does not know the new residence address or location, the registrant shall inform the last registering agency or agencies that he or she is moving within five working days of the move, and shall later notify the agency or agencies of the new address or location within five working days of moving into the new residence address or location, whether temporary or permanent. The law enforcement agency or agencies shall, within three working days after receipt of this information, forward a copy of the change of address information to the Department of Justice. The Department of Justice shall forward appropriate registration data to the law enforcement agency or agencies having local jurisdiction of the new place of residence.~~

~~(2) If the person's new address is in a Department of the Youth Authority facility or a state prison or state mental institution, an official of the place of incarceration, placement, or commitment shall, within 90 days of receipt of the person, forward the registrant's change of address information to the Department of Justice. The agency need not provide a physical address for the registrant but shall indicate that he or she is serving a period of incarceration or commitment in a facility under the agency's jurisdiction. This paragraph shall apply to persons received in a Department of the Youth Authority facility or a state prison or state mental institution on or after January 1, 1999. The Department of Justice shall forward the change of address information to the agency with which the person last registered.~~

~~(3) If any person who is required to register pursuant to this section changes his or her name, the person shall inform, in person, the law enforcement agency or agencies with which he or she is currently registered within five working days. The law enforcement agency or agencies shall forward a copy of this~~

~~information to the Department of Justice within three working days of its receipt.~~

~~(g) (1) Any person who is required to register under this section based on a misdemeanor conviction or juvenile adjudication who willfully violates any requirement of this section is guilty of a misdemeanor punishable by imprisonment in a county jail not exceeding one year.~~

~~(2) Except as provided in paragraphs (5), (7), and (9), any person who is required to register under this section based on a felony conviction or juvenile adjudication who willfully violates any requirement of this section or who has a prior conviction or juvenile adjudication for the offense of failing to register under this section and who subsequently and willfully violates any requirement of this section is guilty of a felony and shall be punished by imprisonment in the state prison for 16 months, or two or three years.~~

~~If probation is granted or if the imposition or execution of sentence is suspended, it shall be a condition of the probation or suspension that the person serve at least 90 days in a county jail. The penalty described in this paragraph shall apply whether or not the person has been released on parole or has been discharged from parole.~~

~~(3) Any person determined to be a mentally disordered sex offender or who has been found guilty in the guilt phase of trial for an offense for which registration is required under this section, but who has been found not guilty by reason of insanity in the sanity phase of the trial, or who has had a petition sustained in a juvenile adjudication for an offense for which registration is required under this section pursuant to subdivision (d), but who has been found not guilty by reason of insanity, who willfully violates any requirement of this section is guilty of a misdemeanor and shall be punished by imprisonment in a county jail not exceeding one year. For any second or subsequent willful violation of any requirement of this section, the person is guilty of a felony and shall be punished by imprisonment in the state prison for 16 months, or two or three years.~~

~~(4) If, after discharge from parole, the person is convicted of a felony or suffers a juvenile adjudication as specified in this subdivision, he or she shall be required to complete parole of at least one year, in addition to any other punishment imposed~~

~~under this subdivision. A person convicted of a felony as specified in this subdivision may be granted probation only in the unusual case where the interests of justice would best be served. When probation is granted under this paragraph, the court shall specify on the record and shall enter into the minutes the circumstances indicating that the interests of justice would best be served by the disposition.~~

~~(5) Any person who has ever been adjudicated a sexually violent predator, as defined in Section 6600 of the Welfare and Institutions Code, and who fails to verify his or her registration every 90 days as required pursuant to subparagraph (E) of paragraph (1) of subdivision (a), shall be punished by imprisonment in the state prison, or in a county jail not exceeding one year.~~

~~(6) Except as otherwise provided in paragraph (5), any person who is required to register or reregister pursuant to clause of (i) of subparagraph (C) of paragraph (1) of subdivision (a) and willfully fails to comply with the requirement that he or she reregister no less than every 30 days is guilty of a misdemeanor and shall be punished by imprisonment in a county jail at least 30 days, but not exceeding six months. A person who willfully fails to comply with the requirement that he or she reregister no less than every 30 days shall not be charged with this violation more often than once for a failure to register in any period of 90 days. Any person who willfully commits a third or subsequent violation of the requirements of subparagraph (C) of paragraph (1) of subdivision (a) that he or she reregister no less than every 30 days shall be punished in accordance with either paragraph (1) of (2) of this subdivision.~~

~~(7) Any person who fails to provide proof of residence as required by subparagraph (E) of paragraph (2) of subdivision (c), regardless of the offense upon which the duty to register is based, is guilty of a misdemeanor punishable by imprisonment in a county jail not exceeding six months.~~

~~(8) Any person who is required to register under this section who willfully violates any requirement of this section is guilty of a continuing offense as to each requirement he or she violated.~~

~~(9) In addition to any other penalty imposed under this subdivision, the failure to provide information required on registration and reregistration forms of the Department of Justice,~~

~~or the provision of false information, is a crime punishable by imprisonment in a county jail for a period not exceeding one year.~~

~~(h) Whenever any person is released on parole or probation and is required to register under this section but fails to do so within the time prescribed, the parole authority, the Youthful Offender Parole Board, or the court, as the case may be, shall order the parole or probation of the person revoked. For purposes of this subdivision, "parole authority" has the same meaning as described in Section 3000.~~

~~(i) Except as provided in Sections 290.01, 290.02, 290.4, and 290.45, and Section 14133.225 of the Welfare and Institutions Code, the statements, photographs, and fingerprints required by this section shall not be open to inspection by the public or by any person other than a regularly employed peace officer or other law enforcement officer.~~

~~(j) In any case in which a person who would be required to register pursuant to this section for a felony conviction is to be temporarily sent outside the institution where he or she is confined on any assignment within a city or county including firefighting, disaster control, or of whatever nature the assignment may be, the local law enforcement agency having jurisdiction over the place or places where the assignment shall occur shall be notified within a reasonable time prior to removal from the institution. This subdivision shall not apply to any person who is temporarily released under guard from the institution where he or she is confined.~~

~~(k) As used in this section, "mentally disordered sex offender" includes any person who has been determined to be a sexual psychopath or a mentally disordered sex offender under any provision which, on or before January 1, 1976, was contained in Division 6 (commencing with Section 6000) of the Welfare and Institutions Code.~~

~~(*l*) (1) Every person who, prior to January 1, 1997, is required to register under this section, shall be notified whenever he or she next reregisters of the reduction of the registration period from 14 to 5 working days. This notice shall be provided in writing by the registering agency or agencies. Failure to receive this notification shall be a defense against the penalties prescribed by subdivision (g) if the person did register within 14 days.~~

~~(2) Every person who, as a sexually violent predator, as defined in Section 6600 of the Welfare and Institutions Code, is required to verify his or her registration every 90 days, shall be notified wherever he or she next registers of his or her increased registration obligations. This notice shall be provided in writing by the registering agency or agencies. Failure to receive this notice shall be a defense against the penalties prescribed by paragraph (5) of subdivision (g).~~

~~(m) The registration provisions of this section are applicable to every person described in this section, without regard to when his or her crime or crimes were committed or his or her duty to register pursuant to this section arose, and to every offense described in this section, regardless of when it was committed.~~

~~SEC. 3.—~~

SEC. 2. Section 290.02 is added to the Penal Code, to read:

290.02. *(a)* Notwithstanding any other law, the Department of Justice shall ~~make available sex offender identification information concerning~~ *provide, upon written request, the names and relevant information pertaining to* persons who are required to register pursuant to Section 290 to any state governmental entity responsible for authorizing or providing publicly funded prescription drugs or other therapies to treat erectile dysfunction of those persons. State governmental entities shall use information received pursuant to this section to protect public safety by preventing the use of prescription drugs or other therapies to treat erectile dysfunction by convicted sex offenders.

(b) Use or disclosure of the information disclosed pursuant to this section is prohibited for any purpose other than that authorized by this section or Section 14133.225 of the Welfare and Institutions Code. The Department of Justice may establish a fee for requests, including all actual and reasonable costs associated with the service.

(c) Notwithstanding any other provision of law, any state governmental entity that is responsible for authorizing or providing publicly funded prescription drugs or other therapies to treat erectile dysfunction may use the sex offender database authorized by Section 290.46 to protect public safety by preventing the use of those drugs or therapies for convicted sex offenders.

~~SEC. 4. Section 290.46 of the Penal Code is amended to read:~~

~~290.46. (a) On or before the dates specified in this section, the Department of Justice shall make available information concerning persons who are required to register pursuant to Section 290 to the public via an Internet Web site as specified in this section. The department shall update the Web site on an ongoing basis. All information identifying the victim by name, birth date, address, or relationship to the registrant shall be excluded from the Web site. The name or address of the person's employer and the listed person's criminal history other than the specific crimes for which the person is required to register shall not be included on the Web site. The Web site shall be translated into languages other than English as determined by the department.~~

~~(b) (1) On or before July 1, 2005, with respect to a person who has been convicted of the commission or the attempted commission of any of the offenses listed in this subdivision or the statutory predecessors of any of these offenses, or any offense which, if committed or attempted to be committed in this state, would have been punishable as one or more of the offenses listed in this subdivision, the Department of Justice shall make available to the public via the Internet Web site his or her names and known aliases, a photograph, a physical description, including gender and race, date of birth, criminal history, the address at which the person resides, and any other information that the Department of Justice deems relevant, but not the information excluded pursuant to subdivision (a).~~

~~(2) This subdivision shall apply to the following offenses:~~

~~(A) Subdivision (b) of Section 207.~~

~~(B) Subdivision (b) of Section 209, except kidnapping to commit robbery.~~

~~(C) Paragraph (2) or (6) of subdivision (a) of Section 261.~~

~~(D) Section 264.1.~~

~~(E) Section 269.~~

~~(F) Subdivision (c) or (d) of Section 286.~~

~~(G) Subdivision (a), (b), or (c) of Section 288, provided that the offense is a felony.~~

~~(H) Subdivision (c) or (d) of Section 288a.~~

~~(I) Section 288.5.~~

~~(J) Subdivision (a) or (j) of Section 289.~~

~~(3) This subdivision shall also apply to any person who has ever been adjudicated a sexually violent predator as defined in Section 6600 of the Welfare and Institutions Code.~~

~~(c) (1) On or before July 1, 2005, with respect to a person who has been convicted of the commission or the attempted commission of any of the offenses listed in paragraph (2) or the statutory predecessors of any of these offenses, or any offense which, if committed or attempted to be committed in this state, would have been punishable as one or more of the offenses listed in this subdivision, the Department of Justice shall make available to the public via the Internet Web site his or her names and known aliases, a photograph, a physical description, including gender and race, date of birth, criminal history, the community of residence and ZIP Code in which the person resides, and any other information that the Department of Justice deems relevant, but not the information excluded pursuant to subdivision (a). However, the address at which the person resides shall not be disclosed until a determination is made that the person is, by virtue of his or her additional prior or subsequent conviction of an offense listed in paragraph (2) of subdivision (a) of Section 290, subject to this subdivision. On or before July 1, 2006, the Department of Justice shall determine whether any person convicted of an offense listed in paragraph (2) also has one or more prior or subsequent convictions of an offense listed in paragraph (2) of subdivision (a) of Section 290, and, for those persons, the Department of Justice shall make available to the public via the Internet Web site the address at which the person resides.~~

~~(2) This subdivision shall apply to the following offenses, provided that the person has one or more prior or subsequent convictions of an offense listed in paragraph (2) of subdivision (a) of Section 290:~~

~~(A) Section 220, except assault to commit mayhem.~~

~~(B) Paragraph (1), (3), or (4) of subdivision (a) of Section 261.~~

~~(C) Paragraph (2) of subdivision (b), or subdivision (f), (g), or (i), of Section 286.~~

~~(D) Paragraph (2) of subdivision (b), or subdivision (f), (g), or (i), of Section 288a.~~

~~(E) Subdivision (b), (d), (e), or (i) of Section 289.~~

~~(d) (1) On or before July 1, 2005, with respect to a person who has been convicted of the commission or the attempted commission of any of the offenses listed in this subdivision or the statutory predecessors of any of these offenses, or of any offense which, if committed or attempted to be committed in this state, would have been punishable as one or more of the offenses listed in this subdivision, the Department of Justice shall make available to the public via the Internet Web site his or her names and known aliases, a photograph, a physical description, including gender and race, date of birth, criminal history, the community of residence and ZIP Code in which the person resides, and any other information that the Department of Justice deems relevant, but not the information excluded pursuant to subdivision (a) or the address at which the person resides.~~

~~(2) This subdivision shall apply to the following offenses:~~

~~(A) Section 220, except assault to commit mayhem, with no prior or subsequent conviction of an offense listed in paragraph (2) of subdivision (a) of Section 290.~~

~~(B) Subdivision (a) of Section 243.4, provided that the offense is a felony.~~

~~(C) Paragraph (1), (3), or (4) of subdivision (a) of Section 261, with no prior or subsequent conviction of an offense listed in paragraph (2) of subdivision (a) of Section 290.~~

~~(D) Section 266, provided that the offense is a felony.~~

~~(E) Section 266c, provided that the offense is a felony.~~

~~(F) Section 266j.~~

~~(G) Section 267.~~

~~(H) Paragraph (2) of subdivision (b), or subdivision (f), (g), or (i), of Section 286, with no prior or subsequent conviction of an offense listed in paragraph (2) of subdivision (a) of Section 290.~~

~~(I) Subdivision (c) of Section 288, provided that the offense is a misdemeanor.~~

~~(J) Paragraph (2) of subdivision (b), or subdivision (f), (g), or (i), of Section 288a, with no prior or subsequent conviction of an offense listed in paragraph (2) of subdivision (a) of Section 290.~~

~~(K) Subdivision (b), (d), (e), or (i) of Section 289, with no prior or subsequent conviction of an offense listed in paragraph (2) of subdivision (a) of Section 290.~~

~~(L) Section 647.6.~~

~~(e) (1) If a person has been convicted of the commission or the attempted commission of any of the offenses listed in this subdivision or the statutory predecessors of any of these offenses, or of any offense which, if committed or attempted to be committed in this state, would have been punishable as one or more of the offenses listed in this subdivision, and he or she has been convicted of no other offense listed in subdivision (b), (c), or (d) other than those listed in this subdivision, that person may file an application for exclusion from the Internet Web site with the Department of Justice. If the department determines that the person meets the requirements of this subdivision, the department shall grant the exclusion and no information concerning him or her shall be made available via the Internet Web site described in this section. He or she bears the burden of proving the facts that make him or her eligible for exclusion from the Internet Web site. However, a person who has filed for or been granted an exclusion from the Internet Web site is not relieved of his or her duty to register as a sex offender pursuant to Section 290 nor from any otherwise applicable provision of law.~~

~~(2) This subdivision shall apply to the following offenses:~~

~~(A) A felony violation of subdivision (a) of Section 243.4.~~

~~(B) Section 647.6, provided the offense is a misdemeanor.~~

~~(C) An offense listed in subdivision (b), (c), or (d) if the offender is eligible for, granted, and successfully completes probation pursuant to Section 1203.066 of the Penal Code.~~

~~(f) The Department of Justice shall make a reasonable effort to provide notification to persons who have been convicted of the commission or attempted commission of an offense specified in subdivision (b), (c), or (d), that on or before July 1, 2005, the department is required to make information about him or her available to the public via an Internet Web site as specified in this section. The Department of Justice shall also make a reasonable effort to provide notice that he or she may be eligible for exclusion from the Internet Web site if he or she may have been convicted of an offense for which exclusion is available pursuant to subdivision (e).~~

~~(g) Notwithstanding Section 6254.5 of the Government Code, disclosure of information pursuant to this section is not a waiver of exemptions under Chapter 3.5 (commencing with Section 6250) of Title 1 of Division 7 of the Government Code and does~~

~~not affect other statutory restrictions on disclosure in other situations.~~

~~(h) (1) Any person who uses information disclosed pursuant to the Internet Web site to commit a misdemeanor shall be subject to, in addition to any other penalty or fine imposed, a fine of not less than ten thousand dollars ($10,000) and not more than fifty thousand dollars ($50,000).~~

~~(2) Any person who uses information disclosed pursuant to the Internet Web site to commit a felony shall be punished, in addition and consecutive to any other punishment, by a five-year term of imprisonment in the state prison.~~

~~(i) Any person who is required to register pursuant to Section 290 who enters the Web site is punishable by a fine not exceeding one thousand dollars ($1,000), imprisonment in a county jail for a period not to exceed six months, or by both that fine and imprisonment.~~

~~(j) (1) A person is authorized to use information disclosed pursuant to this section only to protect a person at risk.~~

~~(2) Except as authorized under paragraph (1) or any other provision of law, use of any information that is disclosed pursuant to this section for purposes relating to any of the following is prohibited:~~

~~(A) Health insurance.~~

~~(B) Insurance.~~

~~(C) Loans.~~

~~(D) Credit.~~

~~(E) Employment.~~

~~(F) Education, scholarships, or fellowships.~~

~~(G) Housing or accommodations.~~

~~(H) Benefits, privileges, or services provided by any business establishment.~~

~~(3) This section shall not affect authorized access to, or use of, information pursuant to, among other provisions, Sections 11105 and 11105.3, Section 8808 of the Family Code, Sections 777.5 and 14409.2 of the Financial Code, Sections 1522.01 and 1596.871 of the Health and Safety Code, Section 432.7 of the Labor Code, Section 290.02 of the Penal Code, and Section 14133.225 of the Welfare and Institutions Code.~~

~~(4) (A) Any use of information disclosed pursuant to this section for purposes other than those provided by paragraph (1)~~

~~or in violation of paragraph (2) shall make the user liable for the actual damages, and any amount that may be determined by a jury or a court sitting without a jury, not exceeding three times the amount of actual damage, and not less than two hundred fifty dollars ($250), and attorney's fees, exemplary damages, or a civil penalty not exceeding twenty-five thousand dollars ($25,000).~~

~~(B) Whenever there is reasonable cause to believe that any person or group of persons is engaged in a pattern or practice of misuse of the information available via the Internet Web site in violation of paragraph (2), the Attorney General, any district attorney, or city attorney, or any person aggrieved by the misuse is authorized to bring a civil action in the appropriate court requesting preventive relief, including an application for a permanent or temporary injunction, restraining order, or other order against the person or group of persons responsible for the pattern or practice of misuse. The foregoing remedies shall be independent of any other remedies or procedures that may be available to an aggrieved party under other provisions of law, including Part 2 (commencing with Section 43) of Division 1 of the Civil Code.~~

~~(k) On or before July 1, 2006, and every year thereafter, the Department of Justice shall make a report to the Legislature concerning the operation of this section.~~

~~(*l*) The Department of Justice and its employees shall be immune from liability for good faith conduct under this section.~~

~~SEC. 5.—~~

SEC. 3. Section 14133.225 is added to the Welfare and Institutions Code, to read:

14133.225. Notwithstanding any other law, the department shall not provide or pay for any prescription drug or other therapy to treat erectile dysfunction for any person who is required to register pursuant to Section 290 of the Penal Code, except to the extent required under federal law. The department may require from the Department of Justice the information necessary to implement this section.

~~SEC. 6.—~~

SEC. 4. This act is an urgency statute necessary for the immediate preservation of the public peace, health, or safety within the meaning of Article IV of the Constitution and shall go into immediate effect. The facts constituting the necessity are:

In order to prevent funding of drugs or other therapies prescribed for erectile dysfunction for use by high-risk sex offenders and to make statutory changes related to automated drug delivery systems, as soon as possible, it is necessary that this act take effect immediately.

O

CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: AB 522 **VERSION: AMENDED JUNE 23, 2005**

AUTHOR: PLESCIA & BOGH **SPONSOR: CARDINAL HEALTH**

RECOMMENDED POSITION: SUPPORT IF AMENDED

SUBJECT: AUTOMATED DRUG DELIVERY SYSTEM: MEDI-CAL COVERAGE: DRUGS OR OTHER THERAPIES: REGISTERED SEX OFFENDERS

Existing Law:

1) Provides for skilled nursing and intermediate care facilities to use an automated drug delivery system to store and distribute drugs, and to track the movement of drugs into and out of the system. (H&S 1261.6)

2) Regulates the manner in which a pharmacist stocks and oversees the removal of drugs from an automated drug delivery system. (H&S 1261.6)

This Bill:

1. Clarifies existing law by:

   a. Defining "pharmacy services" as the provision of both routine and emergency drugs and biologicals to meet the needs of the patient.

   b. Requiring a pharmacist reviewing an order for a drug to check for contraindications and adverse drug reactions when an automated drug delivery system is used.

   c. Limiting access by licensed personnel to an automated drug delivery system to the prescribed drug authorized by the pharmacist and specific to the patient.

   (H&S 1261.6 Amended)

2. Prohibits the State Department of Health Services (DHS) from providing or pay for any prescription drug or therapy to treat erectile dysfunction for any Medi-Cal recipient required to register pursuant to these provisions, except to the extent it is required under federal law.

   (Penal Code 290.02 Added)

3. Requires the Department of Justice (DOJ) to make available sex offender identification information concerning persons required to register under these provisions to any state governmental entity responsible for authorizing or providing publicly funded prescription drugs or other therapies to treat erectile dysfunction of these persons.

   (Welfare and Institutions Code14133.225 Added)

Comment:

1) Author's Intent. The author's intent is to provide clean-up language for AB 2184 (Chapter 342, Statutes of 2004), Automated Dispensing Devises. This language was requested by the Department of Health Services.

2) Legislative History. AB 2184 (Chapter 342, Statutes of 2004), Automated Dispensing Devises, expanded the use of automated drug delivery system in skilled nursing facilities. The board supported AB 2184.

3) Proposed Amendment.

Add the words "and dosage" to H&S Section 1261.6 on page 4, line 33 to read:

> "After the pharmacist reviews the prescriber's order, access by licensed personnel to the automated drug delivery system shall be limited only to the drug and dosage as ordered by the prescriber and reviewed by the pharmacist and that is specific to the patient."

4) Substantive Amendments since the April 27th Board Meeting. Two provisions were added that would prohibit the state from providing erectile dysfunction medication to sex offender. These amendments are in response to recent directives (May 2005) from the federal government and Governor Schwarzenegger to immediately stop the state from providing known sex offenders with taxpayer-funded medications to treat erectile dysfunction.

5) Support & Opposition.

Support: Health and Human Services Agency
AmerisourceBergen
California Department of Mental Health
California Medical Association
Cardinal Health
Crestwood Behavioral Health, Inc.

Opposition: None on file.

6) History.

2005

June 23	From committee chair, with author's amendments: Amend, and re-refer to committee. Read second time, amended, and re-referred to Com. on PUB. S.
June 21	Withdrawn from committee. Re-referred to Com. on RLS.
June 15	From committee: Do pass, and re-refer to Com. on B., P. & E.D. with recommendation: To Consent Calendar. Re-referred. (Ayes 10. Noes 0.).
June 6	From committee chair, with author's amendments: Amend, and re-refer to committee. Read second time, amended, and re-referred to Com. on HEALTH.
June 6	In committee: Hearing postponed by committee.
May 26	Referred to Coms. on HEALTH and B., P. & E.D.
May 5	In Senate. Read first time. To Com. on RLS. for assignment.
May 5	Read third time, passed, and to Senate. (Ayes 73. Noes 0. Page 1405.)
Apr. 28	Read second time. To Consent Calendar.
Apr. 27	From committee: Do pass. To Consent Calendar. (April 26).
Apr. 6	From committee: Do pass, and re-refer to Com. on B. & P. with recommendation: To Consent Calendar. Re-referred. (Ayes 11. Noes 0.) (April 5).
Mar. 30	Re-referred to Com. on HEALTH.
Mar. 29	From committee chair, with author's amendments: Amend, and re-refer to Com. on HEALTH. Read second time and amended.
Feb. 28	Referred to Coms. on HEALTH and B. & P.
Feb. 17	From printer. May be heard in committee March 19.
Feb. 16	Read first time. To print.

AB 522

As Amended June 23, 2005

SENATE COMMITTEE ON PUBLIC SAFETY
Senator Elaine K. Alquist, Chair A
2005-2006 Regular Session B
Penal, Welfare and Institutions Codes (URGENCY)

REGISTERED SEX OFFENDERS :
MEDI-CAL COVERAGE FOR SPECIFIED CONDITIONS
HISTORY

Source: Health and Human Services Agency; Department of Health Services
Prior Legislation: None
Support: California Department of Corrections
Opposition:None known
Assembly Floor Vote: N/A

KEY ISSUES

SHOULD THE Department of Health Services ("DHS") BE PROHIBITED from paying for any prescription drug or other therapy to treat erectile dysfunction for registered sex offenders, as specified?

SHOULD THE Department of Justice BE AUTHORIZED TO share information with DHS concerning registered sex offenders for this purpose, as specified?

PURPOSE

The purpose of this bill is to 1) prohibit the Department of Health Services ("DHS") from paying for any prescription drug or other therapy to treat erectile dysfunction for registered sex offenders, as specified; 2) authorize the Department of Justice to share information with DHS concerning registered sex offenders for this purpose, as specified; and 3) make unrelated substantive changes to the law concerning pharmacy services.

Current law generally requires people who have been convicted of specified sex offenses to register at least annually with the chief of police of the city in which he or she is residing, or the sheriff of the county if where he or she is residing is located in an unincorporated area or city that has no police department, and, additionally, with the chief of police of a campus of the University of California, the California State University, or community college if he or she is residing upon the campus or in any of its facilities, within five working days of coming into, or changing his or her residence within, any city, county, or city and county, or campus in which he or she temporarily resides, for the rest of his or her life while

residing in California, or while attending school or working in California, as specified. (Penal Code 290.)

Current law expressly provides that except as specifically allowed, the statements, photographs, and fingerprints required by this provision shall not be open to inspection by the public or by any person other than a regularly employed peace officer or other law enforcement officer. (Penal Code 290(i).)

Under current law , the Department of Justice ("DOJ") is required to make information about registered sex offenders available to the public via an Internet Web site, as specified. (Penal Code 290.46.)

Current law specifically provides that except as authorized, use of any information that is disclosed pursuant to these provisions for purposes relating to any of the following is prohibited:

Health insurance;
Insurance;
Loans;
Credit;
Employment;
Education, scholarships, or fellowships;
Housing or accommodations; and
Benefits, privileges, or services provided by any business establishment. (Penal Code 290.469j)(2).)

Current law provides that the Medi-Cal Benefits Program comprises a department-administered uniform schedule of health care benefits. (Welfare and Institutions Code ("WIC") 14131; see 14132.) Current law provides that the "purchase of prescribed drugs is covered subject to the Medi-Cal List of Contract Drugs and utilization controls." (WIC 14132(d).)

This bill would provide that, notwithstanding any other law, DHS "shall not provide or pay for any prescription drug or other therapy to treat erectile dysfunction for any person who is required to register pursuant to Section 290 of the Penal Code, except to the extent required under federal law."

This bill would provide that DHS "may require from the Department of Justice the information necessary to implement this section."

This bill would provide that, "notwithstanding any other law, DOJ would be required to provide, upon written request, the names and relevant information pertaining to persons who are required to register pursuant to Section 290 to any state

governmental entity responsible for authorizing or providing publicly funded prescription drugs or other therapies to treat erectile dysfunction of those persons. State governmental entities shall use information received pursuant to this section to protect public safety by preventing the use of prescription drugs or other therapies to treat erectile dysfunction by convicted sex offenders."

This bill would provide that the use "or disclosure of the information obtained pursuant to this section is prohibited for any purpose other than authorized," as specified in this bill.

This bill would authorize DOJ to establish a fee for requests including all actual and reasonable costs associated with the service.

This bill additionally would provide that "(n)otwithstanding any other law, any state governmental entity responsible for authorizing or providing publicly funded prescription drugs or other therapies to treat erectile dysfunction may use the sex offender data base authorized by Section 290.46 (the Megan's Law Web site) to protect public safety by preventing the use of such drugs or therapies to convicted sex offenders."

This bill is an urgency measure.

COMMENTS

1. Stated Need for This Bill

The author states:

> AB 522 would give state agencies access to the information necessary to ensure that taxpayers do not finance erectile dysfunction treatments for known sex offenders. Federal guidelines prohibit state Medicaid programs (Medi-Cal in California) from covering erectile dysfunction treatments for convicted sex offenders, and California could be subject to financial penalties if Medi-Cal does not comply with these guidelines. Without access to the registered sex offender database, state agencies will have no way of knowing if a beneficiary should be denied access to such treatments.
>
> As Governor Schwarzenegger correctly noted in his executive order on May 26, 2005, this is also a public safety issue. We have an obligation to exercise an abundance of caution and ensure that state agencies have access to the criminal databases necessary to prevent the use of these treatments by

known sex offenders.

2. What This Bill Would Do

As explained in detail above, this bill would prohibit DHS from providing or paying for any prescription drug or therapy to treat erectile dysfunction for a registered sex offender. The bill would provide a mechanism for DHS to access, either by using the Megan's Law Web site or obtaining information from DOJ, information from DOJ identifying persons who are registered sex offenders. This bill also would authorize DOJ to establish a fee for its costs associated with providing this information.

3. Background - Medicaid, Erectile Dysfunction Drugs and Registered Sex Offenders

Numerous press accounts this Spring reported that registered sex offenders in at least 14 states got Medicaid-paid prescriptions for Viagra and other prescription drugs used to treat erectile dysfunction. In response to these and other reports, on May 23 of this year the Center for Medicaid and State Operations issued a "guidance to remind states there are a number of options to prevent the inappropriate use of such drugs and to inform states that we believe they should restrict the coverage of such drugs in the case of individuals convicted of a sex offense. . . . We believe that, . . . the use of these drugs in the case of a sex offender is not appropriate and Medicaid should not pay for the cost of such drugs in such circumstances.

> Effective immediately, states should use their drug use review program and procedures . . . and work with physicians and pharmacists to prevent inappropriate Medicaid payment for such drugs in the case of a sex offender. Failure to perform such a review and implement appropriate controls may result in sanctions.<1>

On May 26, 2005, Governor Schwarzenegger announced that he had issued a directive to all applicable state agencies in California to immediately stop providing known sex offenders with taxpayer-funded medications such as Viagra, Levitra or Cialis, to treat erectile dysfunction ("ED").

It is estimated that 137 registered sex offenders in California may have been prescribed ED drugs under Medi-Cal in the last year.

4. Background: ED Treatment

The following information, compiled by the Senate Office of Research, explains the purpose and effect of Viagra, which is a

commonly-used prescription drug for ED.

From the FDA's Center for Drug Evaluation and Research :

Viagra is used to treat impotence in men. Viagra increases the body's ability to achieve and maintain an erection during sexual stimulation. How does Viagra work? An erection is the result of an increase in blood flow into certain internal areas of the penis. Viagra works by enhancing the

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<1> Letter dated May 23, 2005 from Dennis G. Smith, Director of the Center for Medicaid and State Operations, Department of Health & Human Services, addressed to "Dear State Medicaid Director."

effects of one of the chemicals the body normally releases into the penis during sexual arousal. This allows an increase of blood flow into the penis.

Patient Summary Information about Viagra from Pfizer :

VIAGRA is a pill used to treat erectile dysfunction (impotence) in men. It can help many men who have erectile dysfunction get and keep an erection when they become sexually excited (stimulated). You will not get an erection just by taking this medicine. VIAGRA helps a man with erectile dysfunction get an erection only when he is sexually excited. VIAGRA does not cure erectile dysfunction. It is a treatment for erectile dysfunction. VIAGRA is not a hormone or an aphrodisiac.

From Aetna InteliHealth :

In most men, erectile dysfunction is caused by inadequate flow of blood into the penis. PDE5 drugs (Viagra) work by helping the blood vessels relax, which increases blood flow. They do not cause an erection without sexual stimulation, and the penis will return to its normal size and flaccid state after ejaculation. They also have no effect on sexual desire (libido) and do not change sensation in the penis. PDE5 drugs are not habit forming or addictive. They do not increase sexual desire or sexual enjoyment, other than by helping a man to achieve and maintain an erection.

5. Background: Sex Offending; ED Drugs and Sex Offense Behavior

Medical treatment for ED, many assert, helps sex offenders commit sex offenses. "The federal government is inadvertently facilitating the sexual assault of children," Laura Ahearn, executive director of Parents for Megan's Law, told the Associated Press earlier this year.<2> In his May 26 press release, Governor Schwarzenegger stated:

> Our first responsibility is to keep our citizens safe, and providing these drugs to known sex offenders is a policy that only threatens more innocent people.

Others, however, contend that drugs treating ED are unrelated to sexual offending:

> Viagra is often misunderstood to be an aphrodisiac - actually it does nothing to enhance sexual motivation, said Dr. Fred Berlin, a psychiatrist at Johns Hopkins University and an expert on the treatment of sex offenders. . . .
>
> Berlin said he's never heard of a sex offender using Viagra to reoffend.<3>

According to a 2004 law review article on sex offender management written by authors from the Center for Effective Public Policy and the Center for Sex Offender Management, the generally accepted treatment approach for sex offenders addresses a broad range of factors, none of which necessarily appear to center on physical performance:

> While historical efforts to treat sex offenders were widely varied, sex offender treatment has been refined significantly over the past few decades, and has a generally accepted approach. At present,

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<2> USA Today, May 23, 2005.
<3> Associated Press, June 22, 2005 (State Helped Pay for Viagra for 137 Sex Offenders.)

> most sex offender treatment programs throughout the country employ cognitive-behavioral methods that include relapse prevention components.
> Contemporary etiological theories suggest that sex offending behaviors are the result of a complex interaction of sociocultural, biological, and psychological processes . As such, sex offender

> treatment is designed to be relatively comprehensive and holistic, with goals that generally include accepting responsibility for sex offending and other harmful behaviors; modifying cognitive distortions that support offending behaviors; managing negative mood or affect; developing positive relationship skills; managing deviant sexual arousal or interest; maintaining control over unhealthy impulses; enhancing empathy for victims; understanding the sequence of events and risk factors associated with offending; and developing effective coping skills to manage identified risk factors.<4>

Sexual assault has come to be generally understood as a crime of power and control. As explained by the federal Office on Violence Against Women on its Web site:

<4> Carter, Bumby and Talbot, SYMPOSIUM: Promoting Offender Accountability and Community Safety through the Comprehensive Approach to Sex Offender Management (34 Seton Hall L. Rev. 1273 (2004) (citations omitted) (emphasis added).)

> The belief that only young, pretty women are sexually assaulted stems from the myth that sexual assault is based on sex and physical attraction. Sexual assault is a crime of power and control and offenders often choose people whom they perceive as most vulnerable to attack or over whom they believe they can assert power.<5>

Similarly, in its Megan's Law Web site, the California Attorney General's Office includes the following fact about sex offenders:

> While some offenders do seek sexual gratification from the act, sexual gratification is often not a primary motivation for a rape offender. Power, control, and anger are more likely to be the primary motivators.<6>

Members of the Committee may wish to explore further the causes of sexual offending, and how the relationship between ED treatments and sexual offending may impact these causes and public safety.

6. Constitutional Considerations

"An ex post facto law is a retrospective criminal statute applying to crimes committed before its enactment, and substantially injuring the accused, by punishing an act innocent when done, or increasing the punishment , or taking away a

defense related to an element of the crime or an excuse or justification for the conduct, or altering the rules of evidence so that a conviction may be obtained on less or different testimony than was required when the crime was committed."<7> In upholding California's sex offender registration laws against an ex post facto challenge, the California Supreme Court reasoned:

<5> http://www.ojp.usdoj.gov/vawo/SexAssaultInfo.htm.
<6> http://www.meganslaw.ca.gov/facts.htm.
<7> 1 Witkin Cal. Crim. Law Intro. Crimes 10.

> The sex offender registration requirement serves an important and proper remedial purpose, and it does not appear that the Legislature intended the registration requirement to constitute punishment. Nor is the sex offender registration requirement so punitive in fact that it must be regarded as punishment, despite the Legislature's contrary intent. Although registration imposes a substantial burden on the convicted offender, this burden is no more onerous than necessary to achieve the purpose of the statute.<8>

Members may wish to discuss whether the provisions of this bill, notwithstanding the stated purposes of public safety contained in its provisions, would be so punitive in fact as to constitute punishment and violate the ex post facto clauses of the California (Art. I 9) and U.S. (Art. I 10) Constitutions.

7. Similar Bill

This bill is similar to AB 240 (Berm?dez), which was amended on June 20, 2005; that measure appears to reflect an earlier version of this bill. Both of these bills are before the Committee on June 28. With respect to limiting ED drugs and treatment for registered sex offenders, these bills appear to be identical in intent. The bills differ in the following respects:

AB 240 is silent on who would pay to identify Medi-Cal ED claims deriving from registered sex offenders; this bill would authorize DOJ to establish a fee for their actual and reasonable costs;

<8> People v. Castellanos, 21 Cal. 4th 785 (1999) (citations omitted).

statute (Penal Code 290) to authorize DOJ to provide the identifying information about registrants to other

state entities, as specified; this bill instead enacts a new section of law to establish this authority;

This bill authorizes limited access to the Megan's Law Web site by state entities performing functions necessary to identify registrants on the Medi-Cal ED drug claim tape; AB 240 does not provide that authority; and

Additional technical drafting differences exist between these bills; AB 522 is generally drafted with more specificity than AB 240.

Attachment 13

AMENDED IN ASSEMBLY JUNE 15, 2005

AMENDED IN SENATE MAY 4, 2005

AMENDED IN SENATE APRIL 12, 2005

AMENDED IN SENATE APRIL 4, 2005

SENATE BILL No. 401

Introduced by Senator Ortiz

February 17, 2005

An act to amend Section 56.05 of the Civil Code, relating to medical information.

LEGISLATIVE COUNSEL'S DIGEST

SB 401, as amended, Ortiz. Medical information: pharmacies: marketing.

Existing law prohibits a provider of health care, a health care service plan, contractor, or corporation and its subsidiaries and affiliates from intentionally sharing, selling, or otherwise using any medical information, as defined, for any purpose not necessary to provide health care services to a patient, except as expressly authorized by the patient, enrollee, or subscriber, as specified, or as otherwise required or authorized by law. Violations of these provisions are subject to a civil action for compensatory and punitive damages, and, if a violation results in economic loss or personal injury to a patient, it is punishable as a misdemeanor. Existing law provides that this prohibition also applies to the marketing of medical information, as defined, excluding from that definition, for these purposes, communications for which the communicator does not receive remuneration from a 3rd party or for specified descriptive purposes, or that are tailored to the circumstances of a particular individual, as specified.

This bill would further provide that marketing includes a written communication that is provided by a pharmacy to a patient about a different drug or treatment than that being dispensed by the pharmacy and that is paid for, or sponsored by, a manufacturer, labeler, or distributor of prescription drugs, except as specified. Because a violation thereof may be punishable as a misdemeanor, the bill 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:

1 SECTION 1. Section 56.05 of the Civil Code is amended to
2 read:
3 56.05. For purposes of this part:
4 (a) "Authorization" means permission granted in accordance
5 with Section 56.11 or 56.21 for the disclosure of medical
6 information.
7 (b) "Authorized recipient" means any person who is
8 authorized to receive medical information pursuant to Section
9 56.10 or 56.20.
10 (c) "Contractor" means any person or entity that is a medical
11 group, independent practice association, pharmaceutical benefits
12 manager, or a medical service organization and is not a health
13 care service plan or provider of health care. "Contractor" does
14 not include insurance institutions as defined in subdivision (k) of
15 Section 791.02 of the Insurance Code or pharmaceutical benefits
16 managers licensed pursuant to the Knox-Keene Health Care
17 Service Plan Act of 1975 (Chapter 2.2 (commencing with
18 Section 1340) of Division 2 of the Health and Safety Code).
19 (d) "Health care service plan" means any entity regulated
20 pursuant to the Knox-Keene Health Care Service Plan Act of
21 1975 (Chapter 2.2 (commencing with Section 1340) of Division
22 2 of the Health and Safety Code).

(e) "Licensed health care professional" means any person licensed or certified pursuant to Division 2 (commencing with Section 500) of the Business and Professions Code, the Osteopathic Initiative Act or the Chiropractic Initiative Act, or Division 2.5 (commencing with Section 1797) of the Health and Safety Code.

(f) (1) "Marketing" means to make a communication about a product or service that encourages recipients of the communication to purchase or use the product or service.

(2) "Marketing" does not include any of the following:

(A) Communications made orally or in writing for which the communicator does not receive direct or indirect remuneration, including, but not limited to, gifts, fees, payments, subsidies, or other economic benefits, from a third party for making the communication.

(B) Communications made to current enrollees solely for the purpose of describing a provider's participation in an existing health care provider network or health plan network of a Knox-Keene licensed health plan to which the enrollees already subscribe; communications made to current enrollees solely for the purpose of describing if, and the extent to which, a product or service, or payment for a product or service, is provided by a provider, contractor, or plan or included in a plan of benefits of a Knox-Keene licensed health plan to which the enrollees already subscribe; or communications made to plan enrollees describing the availability of more cost-effective pharmaceuticals.

(C) Communications that are tailored to the circumstances of a particular individual to educate or advise the individual about treatment options, and otherwise maintain the individual's adherence to a prescribed course of medical treatment, as provided in Section 1399.901 of the Health and Safety Code, for a chronic and seriously debilitating or life-threatening condition as defined in subdivisions (d) and (e) of Section 1367.21 of the Health and Safety Code, if the health care provider, contractor, or health plan receives direct or indirect remuneration, including, but not limited to, gifts, fees, payments, subsidies, or other economic benefits, from a third party for making the communication, if all of the following apply:

(i) The individual receiving the communication is notified in the communication in typeface no smaller than 14-point type of

the fact that the provider, contractor, or health plan has been remunerated and the source of the remuneration.

(ii) The individual is provided the opportunity to opt out of receiving future remunerated communications.

(iii) The communication contains instructions in typeface no smaller than 14-point type describing how the individual can opt out of receiving further communications by calling a toll-free telephone number of the health care provider, contractor, or health plan making the remunerated communications. No further communication may be made to an individual who has opted out after 30 calendar days from the date the individual makes the opt out request.

(3) ~~"Marketing"~~ *Notwithstanding any other provision of law, "marketing"* includes a written communication that is provided to a pharmacy patient by a pharmacist or by pharmacy personnel, in conjunction with the dispensing of a prescription drug or prescribed treatment therapy, that includes the trade name or commercial slogan for any prescription drug, prescribed treatment therapy, or over-the-counter medication other than the prescription drug or prescribed treatment therapy being dispensed, if the communication is paid for or sponsored, directly or indirectly, by a manufacturer, labeler, or distributor of prescription drugs. This paragraph shall not apply when a trade name or commercial slogan for a prescription drug, prescribed treatment therapy, or over-the-counter medication is included in a written communication for the sole purpose of ~~identifying a potential adverse drug interaction with the prescription drug or prescribed treatment therapy being dispensed.~~ *providing information about drug interactions, reported or potential adverse events, or any other information necessary to ensure the health and safety of the patient, or is part of a package insert that has been approved by the federal Food and Drug Administration to be distributed together with a prescription drug.*

(g) "Medical information" means any individually identifiable information, in electronic or physical form, in possession of or derived from a provider of health care, health care service plan, pharmaceutical company, or contractor regarding a patient's medical history, mental or physical condition, or treatment. "Individually identifiable" means that the medical information includes or contains any element of personal identifying

information sufficient to allow identification of the individual, such as the patient's name, address, electronic mail address, telephone number, or social security number, or other information that, alone or in combination with other publicly available information, reveals the individual's identity.

(h) "Patient" means any natural person, whether or not still living, who received health care services from a provider of health care and to whom medical information pertains.

(i) "Pharmaceutical company" means any company or business, or an agent or representative thereof, that manufactures, sells, or distributes pharmaceuticals, medications, or prescription drugs. "Pharmaceutical company" does not include a pharmaceutical benefits manager, as included in subdivision (c), or a provider of health care.

(j) "Provider of health care" means any person licensed or certified pursuant to Division 2 (commencing with Section 500) of the Business and Professions Code; any person licensed pursuant to the Osteopathic Initiative Act or the Chiropractic Initiative Act; any person certified pursuant to Division 2.5 (commencing with Section 1797) of the Health and Safety Code; any clinic, health dispensary, or health facility licensed pursuant to Division 2 (commencing with Section 1200) of the Health and Safety Code. "Provider of health care" does not include insurance institutions as defined in subdivision (k) of Section 791.02 of the Insurance Code.

SEC. 2. 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.

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CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: SB 401 **VERSION: AMENDED JUNE 15, 2005**

AUTHOR: ORTIZ **SPONSOR: CA. PUBLIC INTEREST RESEARCH GROUP**

RECOMMENDED POSITION: NONE

SUBJECT: MEDICAL INFORMATION: PHARMACIES: MARKETING

Existing Law:

1) Defines marketing as "communication about a product or service that encourages recipients of the communication to purchase or use the product or service."

2) Excludes the following from the definition of marketing:

a. Communications made orally or in writing for which the communicator does not receive direct or indirect remuneration from a third party for making the communication.

b. Communications made to current enrollees solely for the purpose of describing a provider's participation in an existing health care provider network or health plan network of a Knox-Keene licensed health plan to which the enrollees already subscribe

c. Communications that are tailored to the circumstances of a particular individual to educate or advise the individual about treatment options, and otherwise maintain the individual's adherence to a prescribed course of medical treatment for a chronic and seriously debilitating or life-threatening condition, if the health care provider, contractor, or health plan receives direct or indirect remuneration from a third party for making the communication, if all of the following apply:

i. The individual receiving the communication is notified in the communication in typeface no smaller than 14-point type of the fact that the provider, contractor, or health plan has been remunerated and the source of the remuneration.

ii. The individual is provided the opportunity to opt out of receiving future remunerated communications.

iii. The communication contains instructions in typeface no smaller than 14-point type describing how the individual can opt out of receiving further communications by calling a toll-free number of the health care provider, contractor, or health plan making the remunerated communications.

(Civil Code 56.05)

This Bill:

Defines "marketing" to include a written communication that is provided to a pharmacy patient by a pharmacist or by pharmacy personnel, in conjunction with the dispensing of a prescription drug or prescribed treatment therapy, that includes the trade name or commercial slogan for any prescription drug, prescribed treatment therapy, or over-the-counter medication other than the prescription drug or prescribed treatment therapy being dispensed, if the:

1. The communication describes includes the name of, or describes biochemical, pharmacological, or other scientific or health information for, any other drug or treatment other than the drug or treatment being dispensed; and
2. The communication is paid for or sponsored, directly or indirectly, by a manufacturer, labeler, or distributor of prescription drugs.

Specifies that this definition does not apply when 1) a trade name or commercial slogan for a prescription drug, prescribed treatment therapy, or 2) over-the-counter medication is included in a written communication for the sole purpose of providing information about drug interactions, reported or potential adverse events, or any other information necessary to ensure the health and safety of the patient, or is part of a package insert that has been approved by the federal Food and Drug Administration to be distributed together with a prescription drug.

(Civil Code 56.05 Amended)

Comment:

1) Author's Intent. The author's intent is to close a loophole that she sees in the law that allows drug manufacturers to distribute biased written information to patients through pharmacists during face-to-face drug consultations. An example would be an pharmacist giving a patient an advertisement, during the face to face consultation, that list other possible drugs that could be taken for the same condition.

2) Background. AB 715 (Chan, Chapter 562, Statutes of 2003), sought to prohibit marketing practices where a health care provider or entity was paid to market a third party's product or service to a patient, using that patient's medical information. While the bill protected consumer privacy, it did not completely deal with issues surrounding third party marketing to consumers. The question arises, does permitting drug companies to pay for advertising or the production of fact sheets used by pharmacists in consultations with patients benefit or harm the consumer?

AB 746 (Mathews, 2003) was proposed as "clean-up" legislation to AB 715. AB 746 would have clarified that pharmacists had the right to provide patient pamphlets with drug manufacture advertising or messages that informed patients of about the drug they were receiving. Pharmacists argued that including advertisements helped pay for the costs of producing the pamphlets and that prohibiting advertising would result in patients receiving less information about the drug they are taking. AB 746 died in the Senate.

Likewise, SB 401 is also being proposed as "clean-up" legislation to AB 715, but unlike AB 746, it takes the position that marketing information from drug manufacturers during face-to-face interaction is bad for the consumer and should therefore be prohibited. Supporters of the measure argue that information from pharmacists should be free from bias and information from drug manufacturers may confuse patients and contradict the information they receive from their doctor.

3) Previous Legislation.

AB 715 (Chan, Chapter 562, Statutes of 2003) Personal Information.

AB 746 (2003) Medical Information: Pharmacies, Marketing; this measure died in the Senate.

4) Support & Opposition

Support: California Public Interest Research Group (sponsor)
California Alliance for Retired Americans
California Labor Federation
Consumers Union

Opposition: The Body
CA Pharmacists Association
CA Retailers Association
Catalina Health Resource; Kaiser Permanente
Nat'l Association of Chain Drug Stores
Nat'l Consumers League
Nat'l Council on Patient Information and Education
Novartis Pharmaceuticals
Pharmaceutical Research and Manufacturers of America
Rite Aid

5) History.

2005

June 28	Set, first hearing. Hearing canceled at the request of author.
June 15	From committee with author's amendments. Read second time. Amended. Re-referred to committee.
June 13	To Coms. on HEALTH and JUD.
May 26	In Assembly. Read first time. Held at Desk.
May 26	Read third time. Passed. (Ayes 23. Noes 13. Page 1190.) To Assembly.
May 25	Read second time. To third reading.
May 24	From committee: Be placed on second reading file pursuant to Senate Rule 28.8.
May 16	Set for hearing May 23.
May 4	Read second time. Amended. Re-referred to Com. on APPR.
May 3	From committee: Do pass as amended, but first amend, and re-refer to Com. on APPR. (Ayes 5. Noes 2. Page 801.)
Apr. 14	Set for hearing April 26.
Apr. 12	Read second time. Amended. Re-referred to Com. on JUD.
Apr. 11	From committee: Do pass as amended, but first amend, and re-refer to Com. on JUD. (Ayes 8. Noes 3. Page 498.)
Apr. 4	From committee with author's amendments. Read second time. Amended. Re-referred to committee.
Mar. 16	Set for hearing April 6.
Feb. 24	To Coms. on HEALTH and JUD.
Feb. 18	From print. May be acted upon on or after March 20.
Feb. 17	Introduced. Read first time. To Com. on RLS. for assignment. To print.

SB 401

As Amended: June 15, 2005

ASSEMBLY COMMITTEE ON HEALTH
Wilma Chan, Chair
SB 401 (Ortiz) -
SUBJECT: Medical information: pharmacies: marketing.

SUMMARY : Includes in the definition of "marketing," under the Confidentiality of Medical Information Act (CMIA), written communications, which pharmacists provide to patients when dispensing prescription drugs, if the communication includes the trade name or commercial slogan for any drug other than the dispensed drug when the cost of the communication is paid, directly or indirectly, by a drug manufacturer or distributor. Specifically, this bill :

1)Defines "marketing," for purposes of the CMIA, to include a written communication that is provided to a pharmacy patient by a pharmacist or by pharmacy personnel, in conjunction with the dispensing of a prescription drug or prescribed treatment therapy, that includes the trade name or commercial slogan for any prescription drug, prescribed treatment therapy, or over-the-counter medication, other than the prescription drug or prescribed treatment therapy being dispensed, if the communication is paid for or sponsored, directly or indirectly, by a manufacturer, labeler, or distributor of prescription drugs.

2)States the provisions of #1) above do not apply when a trade name or commercial slogan for a prescription drug, prescribed treatment therapy, or over-the-counter medication is included in a written communication for the sole purpose of providing information about drug interactions, reported or potential adverse events, or any other information necessary to ensure the health and safety of the patient, or is part of a package insert that has been approved by the federal Food and Drug Administration (FDA) to be distributed together with a prescription drug.

EXISTING LAW :

1)Establishes the CMIA which prohibits any provider of health care, health care service plan, contractor, or corporation from intentionally using any medical information, as defined, for any purpose not necessary to provide health care services to the patient, except as expressly authorized by the patient, or as otherwise required or authorized by law.

2)Defines "marketing," for the purposes of the CMIA, as making a

communication about a product or service that encourages recipients of the communication to purchase or use the product or service. Excludes from the definition of marketing the following:

a) Communications made orally or in writing for which the communicator does not receive direct or indirect remuneration;

b) Communications made to current enrollees of a health care service plan for purposes related to payment for a product or service, describing plan benefits or services, or describing the availability of more cost effective pharmaceuticals; and,

c) Communications that are tailored to the circumstances of a particular individual who is in a disease management program for a chronic and seriously debilitating or life threatening condition, even if the health care provider receives direct or indirect remuneration, if the individual receiving the communication is notified in at least 14-point type that the provider has been remunerated, the source of that remuneration, and that the patient has the opportunity to opt out of receiving future remunerated communications.

3)Establishes, under federal law, the FDA to regulate the manufacture, labeling, sale, and distribution of drugs in the United States. Requires the FDA, before any other initiatives can be proposed, to evaluate the success of a public-private action plan with a goal that useful written information be given to at least 75% of persons receiving new prescriptions by the year 2000 and 95 percent by 2006

4)Under the federal Health Insurance Portability and Accountability Act (HIPAA), provides a federal floor of protections for protected medical information and permits states to enact greater protections.

FISCAL EFFECT : Unknown. This bill was approved by the Senate Appropriations Committee pursuant to Senate Rule 28.8.

COMMENTS :

1)PURPOSE OF THIS BILL . According to the author, this bill is needed because consumers rely on their pharmacists for accurate, unbiased information. Information received from pharmacists should be objective and free from advertisements that are specifically designed to build name recognition. The author believes that injecting direct to consumer

advertisements within these communications is wholly inappropriate and can be mistaken as a tacit endorsement of a particular product or drug or an implicit veto of a physician's recommended course of treatment. This is particularly egregious given that patients receive these advertisements after their physicians have examined them and prescribed the most appropriate treatment in their professional opinion. The author states that physicians, not drug manufacturers, should be a patient's best resource in determining the most appropriate and cost effective course of treatment to meet their health needs, and that this bill will ensure that pharmacy communications are not used as yet another vehicle to steer consumers to unnecessary and high-priced prescription drugs. Finally, the author notes that studies show that direct to consumer advertising is a key contributor to the rising costs of prescription drugs. Additionally, these types of advertisements can interfere with the doctor-patient relationship by leading patients to self diagnose and demand specific brand name drugs and treatments. According to the author, written communications that generally inform patients to consult their physicians about whether alternative drugs or other, treatments may be beneficial to them without promoting a specific drug will facilitate better patient-physician dialogue and lead to more appropriate prescribing.

2)BACKGROUND . In response to the growing practice of third-party companies paying health care providers to market products or services to patients using the patients' medical information, the California State Office of HIPAA Implementation and the California Medical Association jointly sponsored AB 715 (Chan), Chapter 562, Statutes of 2003, to address improper use medical information. AB 715 amended existing provisions of the CMIA to prohibit the use or sharing of medical information without patient authorization, and specified that a health care provider could not use medical information for marketing purposes without authorization, with certain exceptions. AB 746 (Matthews) of 2004 attempted to create additional exceptions to AB 715's definition of "marketing" by specifying that written communications provided to a pharmacy patient during a face-to-face interaction with the pharmacist were not "marketing" so long as: a) the communication helped pharmacists meet specified federal information distribution requirements; b) the majority of the communication related to the drug being dispensed; c) the pharmacist was available to answer questions; d) specific identifying information was not used to determine the sponsored content; and, e) any sponsored information was clearly labeled as such. AB 746 died on the Senate floor after opponents argued that it would be inappropriate for pharmacists to include advertisements in what should be

unbiased information packets.

3)HIPAA . HIPAA was primarily enacted in 1996 to improve health insurance access for persons changing employers or leaving the workforce, but also contained administrative simplification provisions and medical information privacy standards. In 2002, pursuant to a HIPAA requirement, the U.S. Department of Health and Human Services (HHS) published it's "Standards for Privacy of Individually Identifiable Health Information: Final Rule" (Standards) in the federal register. Under the Standards, in most cases, a health care provider or health plan must first obtain an authorization from the patient for any use or disclosure of protected health information for marketing. Under the Standards, marketing information is defined to include situations where a health care provider or health plan discloses protected health information to another entity in exchange for direct or indirect remuneration so that the other entity can make a communication about its own product or services to the patients of the provider or plan. In some cases, such as those addressed in AB 715 and in this bill, information is not disclosed to the third party, yet marketing still occurs. Under HIPAA, this marketing is permissible without patient authorization. However, HIPAA is only a floor, and states may enact greater privacy protections.

4)PHARMACY COMMUNICATIONS . Current state and federal law requires drug manufacturers to provide, and pharmacists to distribute, written communications, commonly referred to as "patient drug information leaflets" or "patient package inserts" to consumers with certain prescription drugs. This information generally contains objective health information related to the appropriate dosage, potential side effects, drug interactions, and other information relevant to the prescribed medication. Although not required for most prescriptions, most pharmacies include information leaflets with all prescriptions they dispense. Some pharmacists' written communications additionally include direct to consumer advertisements for competing or adjunctive drugs and treatment therapies other than the medication the patient's physician has prescribed. Drug manufacturers pay third party companies to have their advertisements included in a "newsletter" which is then provided to pharmacy patients when their prescriptions are filled. The pharmacist enters the patient's gender, drug, and age into a software program which will then generate a threefold pamphlet containing specified utilization and safety information as required by state and federal law, health tips from federal and state agencies or private health organizations, and targeted direct to consumer advertisements for alternative or adjunctive medications based on the information provided. The third party company provides the

pharmacy with the software and paper free of charge.

One of the major companies providing these newsletters is Catalina Health Resource (CHR), a subsidiary of Catalina Marketing. CHR provided materials to the committee describing its PatientLink newsletters. According to CHR, PatientLink is the nation's leading newsletter that provides customized health care information for patients. Each month one hundred million patients receive a PatientLink newsletter when picking up their prescriptions. CHR states that less than one in four PatientLink newsletters contain sponsored messaging, which is always or almost always clearly disclosed. According to CHR's website, 19 of the top 20 pharmaceutical companies use PatientLink and the company's network includes more than 15,000 pharmacy outlets. The website includes a demonstration of how PatientLink can help encourage patients to switch from one drug to another and claims that drug companies using PatientLink on average experience a prescription volume gain of 8.1% and a return on investment of greater than three to one.

5)SUPPORT . Supporters argue that pharmacists are regarded as the most trusted health care professional and contend that such communications this bill seeks to ban could be mistaken as a tacit endorsement of a particular drug or an implicit veto of a physician's recommended course of treatment. Supporters believe that patients have a reasonable expectation that the information they receive from the pharmacy is objective. They insist that inserting paid advertising into the pharmacist-patient interaction betrays that expectation and changes the role of the pharmacist from unbiased information provider to drug company salesperson. They believe people take very seriously what is placed in prescription bags, believing important information is contained for them as patients. Supporters argue that this kind of advertising can undermine consumer confidence in the essential scientific information about dosage, side effects, and potential drug interactions that patients do need to receive from their pharmacists. Supporters also believe that since this advertising may conflict with a doctor's instructions for other prescriptions, it can also create a great deal of confusion for elderly patients, the chronically ill, or those with a large number of prescriptions. Supporters argue that drug safety concerns call for increased caution in expanding prescription drug marketing. They cite the recent highly publicized recall of the popular painkiller Vioxx, which they insist affected far more consumers than it should have due to aggressive direct-to-consumer advertising.

6)OPPOSITION . Opponents argue that this bill will interfere

with the distribution of valuable information to the detriment of patients. They believe consumers should receive as much information as possible about their conditions, their prescription drugs and treatment alternatives, including compliance and persistence messaging, disease state management materials, and information about alternative or adjunctive therapies. They report that pharmaceutical manufacturers often underwrite the costs of many of these written in-pharmacy communications. Rite Aid argues that most pharmacies find it financially necessary to contract with a third party company to prepare and format the material included in a customer insert because there are thousands of drugs that require background information and information related to these drugs is updated on a regular basis. Because of the significant expense of providing this information,

pharmacies often turn to drug manufacturers to sponsor these communications. Opponents argue that in evaluating sponsored patient communications, the focus should be on the value of the content and not on whether some part of the message has been sponsored. A number of HIV-AIDS organizations argue that this bill will severely restrict the free flow of useful health care information that is now available free of cost with every prescribed medication. Opponents state that pharmacies have experienced significant cuts in their reimbursement rates from the state's Medi-Cal program, workers' compensation and private payers, while paying increasingly more for prescription drugs. They believe this bill represents another operating cost that would have to be shouldered by pharmacies whose margins are already tightly constrained. Finally, opponents argue that this bill is contrary to HIPAA privacy regulations which state that refill reminders and information about treatment options are part of the patient's treatment, and that patients are considered to have consent to by filling the original prescription.

7)CONCERNS AND PROPOSED AMENDMENTS . The National Council on Patient Information and the National Consumers League (NCL) are concerned that this bill will impede the flow of useful medicine information to consumers. Both organizations refer to NCL's ten best practice principles for health care communications provided by pharmacies as standards that protect patients. Among those 10 principles are identifying sponsorship and providing patients with an opportunity to opt out. NCL and La Clinica expressly request the bill be amended to allow sponsored pharmacy communications if sponsorship identification and opt-out provisions are included. Opponents of this bill, prior to its passage in the Senate, proposed an amendment to require clear disclosure of sponsorship. The AIDS Legal Referral Panel and the California Hispanic Health Care Association express concerns that this bill will preclude

patients from receiving important information.

8)LEGISLATIVE COUNSEL OPINION . The author has requested an opinion from Legislative Counsel asking if this bill in any way would prohibit individuals with chronic and seriously debilitating or life-threatening conditions, such as HIV-AIDS, from receiving information about alternative treatment options.

9)QUESTIONS AND COMMENTS . This bill addresses issues at the intersection of health care information, medical privacy, and pharmaceutical marketing and raises the following questions: Do patients have a right to receive this information without accompanying marketing messages from third parties (generally other drug companies)? Should pharmacies be expected to pay for this material? Aren't consumers now paying for these communications in the prices that consumers, employers, and government are paying for prescription drugs? How often are the "advertised" alternative drugs included in the communication a more expensive brand-name drug that is being suggested to replace a less expensive generic?

10)DOUBLE REFERRAL . This bill has been double-referred. Should this bill pass out of this committee, it will be referred to the Assembly Judiciary Committee.

REGISTERED SUPPORT / OPPOSITION :

Support

California Public Interest Research Group (sponsor)
California Alliance for Retired Americans
California Dialysis Council
California Labor Federation
Consumers Union
Gray Panthers
Greenlining Institute
Latino Coalition for a Healthy California

Opposition

AIDS Emergency Fund
Bay Area Young Positives
Black AIDS Institute
California Pharmacists Association
California Retailers Association
Catalina Health Resource
MAGNET
National Association of Chain Drug Stores
Novartis Pharmaceuticals
Pharmaceutical Research and Manufacturers of America

Rite Aid
San Francisco Kaiser HIV/AIDS Advisory Board
Shanti
Stop AIDS Project San Francisco
TheBody.com
2 individuals

Analysis Prepared by : John Gilman / HEALTH / (916) 319-2097

Attachment 14

AMENDED IN SENATE JUNE 30, 2005

AMENDED IN SENATE JUNE 15, 2005

Senate Concurrent Resolution No. 49

Introduced by Senator Speier

May 17, 2005

Senate Concurrent Resolution No. 49—Relative to medication errors.

LEGISLATIVE COUNSEL'S DIGEST

SCR 49, as amended, Speier. Medication errors panel.

This measure would create a panel to study the causes of medication errors and recommend changes in the health care system that would reduce errors associated with the delivery of prescription and over-the-counter medication to consumers. The measure would require the panel to convene by October 1, 2005, and to submit to the Senate Committee on Health a preliminary report by March 1, 2006, and a final ~~by~~ report by June 1, 2006.

Fiscal committee: no.

WHEREAS, Numerous studies establish that medication errors cause injury and death to patients and consumers; and

WHEREAS, The Institute of Medicine estimates the cost for treatment of drug-related morbidity and mortality may run nearly $77 billion a year nationally; and

WHEREAS, Research demonstrates that most injuries resulting from medication errors are not the fault of any individual health care professional, but rather represent the failure of a complex health care system; and

WHEREAS, The Federal Food and Drug ~~Agency~~ *Administration* has approved 122 chemical compounds since

2002, and over 17,000 existing trade and generic names of products exist, many of which sound alike or are spelled alike; and

WHEREAS, These products are also packaged and distributed in similar shapes and forms; and

WHEREAS, The demand for prescription drugs is expected to substantially increase; and

WHEREAS, Medication errors occur in all settings in which prescription drug products are prescribed, dispensed, furnished, ordered, or otherwise provided; and

WHEREAS, Many factors contribute to a poor understanding by many consumers and patients about their prescriptions, including frequent switching of generic brands that are each different colors and shapes so that the same drug looks different and confuses the patient making it hard to easily spot mistakes; overworked pharmacists; reduced time with physicians for patients to be given important drug information; patients seeing multiple physicians that may be unaware of each other's care plans; patients often using vitamins, herbs, and over-the-counter drugs that can react with the medications they take and that both the physician and pharmacist do not know about; and

WHEREAS, Research has demonstrated that improved communication between patients and their health professionals is the most effective means of reducing errors and drug misadventures and improving health care outcomes; now, therefore, be it

Resolved by the Senate of the State of California, the Assembly thereof concurring, That a special panel be formed to study causes of medication errors; and be it further

Resolved, That the Legislature shall convene the panel no later than October 1, 2005; and be it further

Resolved, That the panel shall recommend improvements, additions, or changes to be constructed and implemented for the significant improvement of the health care system by reducing errors associated with the delivery of prescription and over-the-counter medications to consumers; and be it further

Resolved, That the panel membership shall consist of appointees of the Senate Committee on Health~~,~~ *and* the Assembly Committee on Health; and be it further

Resolved, That the Speaker of the Assembly shall appoint to the panel a member of the faculty of a school of pharmacy, a representative of the California Pharmacists Association, a representative of the California Association of Health Plans, a representative of the Pharmaceutical Research and Manufacturers of America, a member of the California Medical Association, a member or representative of the Assembly Republican Caucus, and a consumer representative; and be it further

Resolved, That the Senate Committee on Rules shall designate the chair and appoint to the panel a representative of the California Retailers Association Chain Drug Committee, a member of the California Society of Hospital Pharmacists, a representative of the Generic Pharmaceutical Association, a representative of a public health organization, a member of the California Nurses Association, a representative of the American Association of Retired People, *a representative of the Consumer Health Care Products Association,* and a member or representative of the Senate Republican Caucus; and be it further

Resolved, That the members of the panel shall not receive compensation, but shall be reimbursed from private sources for necessary travel expenses for the purpose of attending meetings of the panel, including any public meetings that the panel schedules; and be it further

Resolved, That the panel shall submit to the Senate Committee on Health a preliminary report of its conclusions and recommendations by March 1, 2006, and a final report of its conclusions and recommendations no later than June 1, 2006; and be it further

Resolved, That the Secretary of the Senate transmit copies of this resolution to the author for appropriate distribution.

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SCR 49

As Amended: June 15, 2005

SENATE HEALTH

COMMITTEE ANALYSIS
Senator Deborah V. Ortiz, Chair

FISCAL: Non-Fiscal
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9
CONSULTANT:
Margolis / ag

SUBJECT

Medication errors: creation of legislative panel

SUMMARY

This resolution makes findings related to the dangers and causes of medication errors, and resolves that a special panel be formed by the California Legislature to study the causes of medication errors and submit a final report to the Senate Committee on Health by June 1, 2006.

ABSTRACT

Existing law:
1.Requires every pharmacy to establish a quality assurance program that documents mediation errors attributable to the pharmacy or its personnel.

This bill:
Includes the following findings:
1.Numerous studies establish that medication errors cause injury and death.

2.The Institute of Medicine estimates annual drug-related morbidity and mortality costs to be approximately $77 million nationally.

3.Research demonstrates that medication errors result from the failures of a complex healthcare system and are not the fault of individual healthcare providers.

4.Over 17,000 trade and generic products exist, for which many of the names are similar, and many are packaged

similarly.

5.Many factors contribute to a poor understanding by patients about their prescriptions.

6.Improved communication between patients and their health professionals is the most effective means of reducing medication errors.

Resolves that:

1.The Legislature convene a special panel to study causes of medication errors no later than October 1, 2005.

2.The panel recommend improvements, additions, or changes to improve the health care system by reducing medication errors.

3.The panel shall consist of appointees of the Health Committees of the Senate and Assembly.

4.The Speaker of the Assembly shall appoint a member of the faculty of a school of pharmacy; representatives of: the California Pharmacists Association, the California Association of Health Plans, the Pharmaceutical Research and Manufacturers of America, the California Medical Association, the Assembly Republican Caucus; and a consumer representative.

5.The Senate Committee on Rules shall designate the panel's chair and appoint representatives from: the California Retailers Association Chain Drug Committee, the Generic Pharmaceutical Association, the California Society of Hospital Pharmacists, a public health organization, the California Nurses Association, the American Association of Retired People, and the Senate Republican Caucus.

6.The panel shall submit to the Senate Committee on Health a preliminary report by March 1, 2006, and a final report by June 1, 2006.

7.The members of the panel shall not receive compensation but shall be reimbursed for travel expenses, and the panel shall be funded by private sources.

FISCAL IMPACT

This is a non-fiscal bill and requires that the panel be funded by private sources.

BACKGROUND AND DISCUSSION

Medical errors

A seminal 1999 report by the Institute of Medicine (IOM), To Err Is Human: Building a Safer Health System, effectively launched a national discussion about the seriousness and gravity of medical errors in this country. The report states that between 44,000 and 98,000 people die in hospitals each year as a result of medical errors that could have been prevented. According to the report, "Preventable medical errors in hospitals exceed attributable deaths to such feared threats as motor-vehicle wrecks, breast cancer, and AIDS." The report describes the high and varied types of costs that result from medical errors, totaling between $17 and $29 billion per year in hospitals nationwide. Other costs cited include: loss of trust in health care; physical and psychological discomforts for patients; loss of morale and frustration by providers; lost worker productivity; and increased school absences by children.

The IOM study explores the causes of medical errors and concludes that "The majority of medical errors do not result from individual recklessness?errors are caused by faulty systems, processes, and conditions that lead people to make mistakes or fail to prevent them." Within this report, the IOM lays out a comprehensive strategy to reduce preventable medical errors, concluding that the ways to prevent these errors already are known. The strategy includes the following four major goals:

1. Establish a national focus to create leadership, research, tools, and protocols to enhance the knowledge base about safety. Specifically, the IOM recommended that Congress create a "Center for Patient Safety, within the Agency for Healthcare Research and Quality (AHRQ), to set national safety goals, develop a research agenda, and develop, disseminate, and evaluate tools for identifying and analyzing errors, among other tasks.

2. Develop a nationwide public mandatory reporting system and encourage health care organizations and practitioners to develop and participate in voluntary reporting systems. State governments would be required to collect standardized information; hospitals would be required to begin reporting first, and eventually all health care organizations would report.

3. Raise performance standards and expectations for improvements in safety through the actions of oversight organizations, professional groups, and group purchasers of health care. The IOM argues that setting and enforcing explicit performance standards for patient safety through regulatory and related mechanisms, such as

licensing, certification, and accreditation can define minimum performance levels for health professionals. The report states that professional societies should become leaders in encouraging and demanding improvements in patient safety, by setting their own performance standards, communicating with members about safety, and collaborating across disciplines. Public and private purchasers are urged to make safety a prime concern in their contracting decisions.

4. Implement safety systems in health care organizations to ensure safe practices at the delivery level. The report states that, "Safety should be an explicit organizational goal that is demonstrated by strong leadership on the part of clinicians, executives, and governing bodies." This includes: designing jobs and working conditions for safety; standardizing and simplifying equipment, supplies, and processes; and enabling care providers to avoid reliance on memory.

According to the IOM, many actions have occurred to implement these strategies since the issuance of the report in 1999, including:

Congress appropriated $50 million to the AHQR to: develop and test new technologies; conduct large-scale demonstration projects; and support new and established multidisciplinary teams of researchers in health-care facilities and organizations.

The National Academy for State Health Policy convened leaders from both the executive and legislative branches of the states to discuss approaches to improving patient safety.

The Leapfrog Group, an association of private and public sector group purchasers, unveiled a market-based strategy to improve safety and quality.

The Council on Graduate Medical Education and the National Advisory Council on Nurse Education and Practice held a joint meeting on educational models to ensure patient safety.

In May of 2005, two of the original authors (Lucien Leape, M.D., and Donald Berwick, M.D.) of To Err is Human published a follow-up study of progress made in the five years following the IOM report. The authors conclude that, "The groundwork for improving safety has been laid in these past five years but progress is frustratingly slow." They also state that small improvements can be seen at the margins, but the overall national situation remains largely the same. This follow-up report cites the following

barriers to change: creating a culture of safety requires changes that physicians may perceive as threats to their autonomy and authority; fear of malpractice liability leads to an unwillingness to discuss or admit errors; the complexity of the health care industry; a lack of leadership; the lack of measures to gauge progress; and the current reimbursement system that rewards less-safe care. Leape and Berwick argue that the single most important next step is to set and adhere to "strict, ambitious, quantitative, and well-tracked national goals."

Medication errors
The National Coordinating Council for Medication Error Reporting and Prevention is dedicated to preventing medical errors specific to medications. The organization includes the following members: AARP, American Health Care Association, American Hospital Association, American Medical Association, American Nurses Association, American Pharmacists Association, American Society of Health-System Pharmacists, Food and Drug Administration, Generic Pharmaceutical Association, and others. This organization has issued recommendations on reducing medication errors in non-health care settings, reducing errors associated with verbal medication orders, reducing errors related to administration of drugs, error-prone aspects of dispensing medications, labeling and packaging of drugs, and more.

The California Pharmacists Association, the sponsor of the bill, writes in support that "SCR 49 will create a credentialed panel to study the systemic causes of these errors, and make substantive recommendations to reduce them for the protection of the public and for healthcare cost reductions." The California Nurses Association states in support that this panel "will bring together a diverse group of individuals to look at the cause of millions of needless consumer deaths or disabilities due to preventable medication errors." Kaiser Permanente writes in support of the bill that, "This panel would be able to take an informed, independent look at new technologies and different processes that could be used to reduce medication errors."

Prior legislation
SR 44 (Burton, 2004) -- requires the Senate to establish the California Commission on the Fair Administration of Justice to study and review the administration of criminal justice in California, to determine the extent to which that process has failed in the past, resulting in wrongful executions or the wrongful convictions of innocent persons. The Commission must be funded privately and make recommendations to the Legislature and

Governor by December 31, 2007.

SCA 39 (Soto, Chapter 142, Statutes of 2001) -- required the Senate Committee on Public Employment and Retirement to convene a panel to study the funding of pharmacy benefits, co-payments, and other benefit structures of the Public Employees' Medical and Hospital Care Act program, and report back to the Committee by June 1, 2002. The sponsor of SCR 49 states that the SCA 39 process was considered successful by those involved and that valuable recommendations were produced by the panel.

Author's amendment
The author would like to offer an amendment in Committee to add to the panel a representative of the Consumer Healthcare Products Association, to be appointed by the Senate Rules Committee.

POSITIONS

Support: California Pharmacists Association (sponsor)
California Nurses Association
Kaiser Permanente

Oppose: None received.

Attachment 15

AMENDED IN SENATE JUNE 23, 2005

AMENDED IN ASSEMBLY MAY 26, 2005

AMENDED IN ASSEMBLY APRIL 18, 2005

AMENDED IN ASSEMBLY APRIL 7, 2005

AMENDED IN ASSEMBLY FEBRUARY 11, 2005

CALIFORNIA LEGISLATURE—2005–06 REGULAR SESSION

ASSEMBLY BILL No. 71

Introduced by Assembly Members Chan and Frommer (Coauthors: Assembly Members Bass, Cohn, Evans, Gordon, Koretz, and Pavley)

January 3, 2005

An act to add Article 7 (commencing with Section 111657) to Chapter 6 of Part 5 of Division 104 of the Health and Safety Code, relating to pharmaceuticals.

LEGISLATIVE COUNSEL'S DIGEST

AB 71, as amended, Chan. Pharmaceuticals: adverse drug reactions: Office of California Drug Safety Watch.

Existing law, the Sherman Food, Drug, and Cosmetic Law, regulates the packaging, labeling, and advertising of food, drugs, and cosmetics, under the administration of the State Department of Health Services.

This bill would establish the Office of California Drug Safety Watch within the department and would require the office, among other duties, to establish a central repository of information about the safety and effectiveness of prescription drugs ~~frequently advertised on television,~~ *that belong to classes of drugs for which there have been*

recently published reports of safety concerns, that have been frequently advertised directly to consumers, and for which there are recently published systematically reviewed evidence-based research that includes research on side effects and safety issues. The bill would require the office to disseminate information to health care professionals and consumers through an Internet Web site~~,~~ *and* to request assistance from the University of California and California State University~~, and to rely on systematically reviewed evidence-based research~~.

This bill would require the department to impose a fee on any manufacturer of drugs sold in the state, in an amount based on the drug manufacturer's market share of the total amount of drugs sold in the state.

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

The people of the State of California do enact as follows:

1 SECTION 1. The Legislature finds and declares all of the
2 following:
3 (a) Since 1997, when the United States Food and Drug
4 Administration (FDA) allowed drug manufacturers to advertise
5 directly to consumers, the amount spent on advertising has risen
6 dramatically.
7 (b) According to the United States General Accounting Office
8 (GAO) report, the pharmaceutical industry spent $2.7 billion in
9 2001 on direct-to-consumer advertising. A December 6, 2004,
10 New York Times report states that such spending has reached
11 $3.8 billion.
12 (c) According to the same GAO report, while overall spending
13 on drug promotion was less than spending on research and
14 development ($19.1 billion versus $30.3 billion), spending on
15 direct-to-consumer advertising is increasing at a faster rate than
16 overall drug promotion spending or spending on research and
17 development. Between 1997 and 2001, the increase in
18 direct-to-consumer advertising was 145 percent compared to a 59
19 percent increase for research and development.
20 (d) Although the FDA is responsible for postmarket
21 surveillance of prescription drugs, numerous concerns have been
22 raised about the adequacy of these efforts.

(e) An unpublished internal FDA study from 2002 revealed that 18 percent of FDA scientists reported being pressured to approve a new drug "despite reservations about the safety, efficacy or quality of the drug."

(f) A 1999 FDA survey and a Kaiser Family Foundation survey both found that more than 50 million people respond to drug advertisements by asking their doctor whether the advertised medications might work for them. At the same time, both surveys showed that almost 60 percent of consumers found the side-effect warnings in these advertisements to be inadequate.

(g) Pressure to get new drugs to market, combined with the vast amount of drug marketing undertaken by manufacturers, make it difficult to address a threat once it is identified. Recent studies linking the use of popular, widely promoted prescription drugs to serious public health concerns point to the need for greater oversight to protect the public.

(h) Drugs that are frequently advertised to consumers present special safety concerns because direct-to-consumer advertising is likely to minimize potential side effects and safety concerns and because advertised drugs are likely to be highly utilized by Californians.

~~(h)~~

(i) Californians do not have a reliable central repository of information about prescription drug safety and effectiveness.

~~(i)~~

(j) California physicians and other prescribers could benefit from a reliable central repository of information about prescription drug safety and effectiveness.

~~(j)~~

(k) Various nationally respected sources of clinical information are available as sources for a central respository of information about prescription drug safety and effectiveness.

~~(k)~~

(l) Safer and more effective prescription drugs within a class may also be among the less expensive prescription drugs within that class, meaning that a reliable central repository of information about prescription drug safety and effectiveness would create opportunities for prescription drug cost savings.

SEC. 2. Article 7 (commencing with Section 111657) is added to Chapter 6 of Part 5 of Division 104 of the Health and Safety Code, to read:

Article 7. Office of California Drug Safety Watch

111657. (a) There is hereby established in the State Department of Health Services the Office of California Drug Safety Watch, which shall do all of the following, to provide Californians with information on the safety and effectiveness of prescription drugs:

(1) Establish a central repository of information about the safety and effectiveness of prescription drugs that are ~~frequently advertised on television.~~ *selected pursuant to subdivision (b). The repository shall not include information about any therapeutic class of drugs that is used primarily to treat mental illness.*

(2) Disseminate information to California health care professionals and consumers through an Internet Web site that shall include links to other relevant Web-based information that has been professionally reviewed and approved. *The Internet Web site shall include the following statement: "Many factors enter into selecting the proper drug for individual patients. Before changing any medication, a patient shall consult with his or her treating physician or other prescriber."*

(3) Ensure that the dissemination of information is done in a culturally competent manner and addresses the differential impact of medications within a class based on gender, age, and ethnicity, when that information is available. *When there is no evidence supporting the differential impact of medication among various demographic groups, it shall be noted on the Internet Web site.*

~~(4) In selecting therapeutic classes of drugs about which to develop information, the office shall choose the four most frequently advertised classes of drugs for which there is recently published systemically reviewed evidence-based research.~~

~~(5) Request appropriate units of the University of California and the California State University to provide assistance.~~

~~(6) Rely on systematically reviewed evidence-based research.~~

~~(b) The office shall coordinate its activities with other state departments and agencies to avoid unnecessary duplication.~~

(b) In selecting therapeutic drugs about which to develop information, the office shall only include classes of drugs that have all of the following characteristics:

(1) Classes of drugs for which there have been recently published reports of safety concerns.

(2) Classes of drugs that have been frequently advertised directly to consumers.

(3) Classes of drugs for which there are recently published systemically reviewed evidence-based research that includes research on side effects and safety issues.

(c) The office shall request the appropriate units of the University of California and the California State University to provide assistance in implementing this article.

(d) The office shall coordinate its activities with other state departments and agencies to avoid unnecessary duplication.

(e) The office shall rely on systemically reviewed evidence-based research.

(f) The process that the office uses to identify relevant research and standards of clinical evidence shall be transparent and publicly available.

111657.1. For purposes of this article, the following terms have the following meanings:

~~(a) "Evidence-based research" means prescription drug research in which the drugs in question have been administered to experimental and control groups and the subsequent effect of the drugs has been observed through those groups.~~

(a) "Evidence-based research" means research that is based on clinical evidence, including therapeutic outcomes, and that uses a hierarchy of evidence to evaluate the reliability of the research. In well-conducted research, the hierarchy of evidence, from highest to lowest, is the system review of randomized clinical trials, individual randomized clinical trials, controlled trials, cohort studies, and case control studies.

(b) "Systematically reviewed" means review of evidence-based research that uses rigorous, unbiased methods to examine the similarities and differences of results across many individual research studies. The goal of a systematic review is to estimate the comparative effectiveness and safety of health care treatments. A systematic approach to reviewing the evidence

increases the reliability of the results, and the transparency of the procedures.

~~(e) "Most frequently advertised classes of drugs" means the therapeutic classes of drugs most frequently advertised on television for the six-month period prior to the date the office begins compiling the drug safety and effectiveness information required by this article. Frequently advertised classes of drugs shall not include any therapeutic class that is used primarily to treat mental illness.~~

111657.2. (a) There is hereby imposed, pursuant to this section, a fee on manufacturers of drugs sold in the state.

(b) (1) The specific fee to be assessed on a drug manufacturer shall be established by the State Department of Health Services, to the maximum extent practicable, on the basis of a drug manufacturer's market share of the total amount of drugs sold in the state.

(2) A fee shall not be assessed on a drug manufacturer that can demonstrate, as determined by the State Department of Health Services, that it does not manufacture drugs that have the characteristics described in subdivision (b) of Section 111657.

(c) The fee shall be assessed and collected annually by the State Board of Equalization in accordance with Part 22 (commencing with Section 43001) of Division 2 of the Revenue and Taxation Code. The fees collected shall be deposited in the Drug Safety Watch Fund, which is hereby established in the State Treasury. Moneys in the fund shall be expended, upon appropriation by the Legislature, for the purposes of this article, including the costs of the State Board of Equalization for collection and administration of fees. All interest earned on the moneys that have been deposited into the Drug Safety Watch Fund shall be retained in the fund.

(d) The fees collected pursuant to this section and the earnings therefrom shall be used solely for the purposes of implementing this article. The department shall not collect fees pursuant to this section in excess of the amount reasonably anticipated by the department to fully implement this article. The department shall not spend more than it collects from the fees, and the earnings thereon, in implementing this article.

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CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: AB 71 **VERSION: AMENDED JUNE 23, 2005**

AUTHOR: CHAN et. al. **SPONSOR: CHAN**

RECOMMENDED POSITION: NO POSITION

SUBJECT: PHARMACEUTICALS: ADVERSE DRUG REACTIONS: OFFICE OF CALIFORNIA DRUG SAFETY WATCH

Existing Law:

The Federal Food, Drug, and Cosmetic Act and the Modernization Act establish the Food and Drug Administration's (FDA) postmarketing and risk assessment programs for adverse drug reactions. The laws also establish mandatory reporting requirements for drug manufacturers about adverse drug reactions.

This Bill:

1) Establishes the Office of California Drug Safety Watch (office) within the Department of Health Services (DHS). (H&S 111657 Added)

2) Requires the office to do all of the following:

   a. Establish a central repository of information about the safety and effectiveness of prescription drugs; the office would not collect information on drugs that are used primarily to treat mental illness.

   b. Disseminate information to health care professionals and consumers through an Internet Web site that would include links to other relevant web-based information that has been professionally reviewed and approved. Requires that website to contain the following statement: "Many factors enter into selecting the proper drug for individual patients. Before changing any medication, a patient shall consult with his or her treating physician or other prescriber."

   c. Assure that the dissemination of information is done in a culturally competent manner and addresses the differential impact of medications within a class based on gender, age, and ethnicity, when that information is available.

   d. Request units of the University of California and the California State University to provide assistance.

   e. Rely on systematically reviewed evidence-based research.

   f. Requires the office to select therapeutic classes of drugs to develop information on, that have 1) been recently published reports of safety concern; 2) been frequently advertised

directly to consumers; and 3) had recently published systemically reviewed evidence-based research that includes research on side effects and safety issues.

(H&S 111657 Added)

3) Requires the office to coordinate its activities with other state departments and agencies to avoid unnecessary duplication. (H&S 111657 Added)

4) Defines the following terms, evidence-based research and systematically reviewed.

(H&S 111657.1 Added)

5) Requires DHS to impose a fee on any manufacturer of drugs sold in the state, in an amount based on the drug manufacturer's market share of the total amount of drugs sold in the state. (H&S 111657.2 Added)

6) Establishes the Drug Safety Watch Fund in the State Treasury. (H&S 111657.2 Added)

Comment:

1) Author's Intent. The author is concerned about drug safety and the perceived inability of the Federal government to take action to warn the public about potentially dangerous drugs.

2) Necessity for Bill? The intent of this legislation is to provide Californians with a reliable central repository of information about prescription drugs safety and effectiveness. This type of information is currently available through many sources, including the FDA, the Oregon Drug Effectiveness Review Project (ODERP), Consumers Union [Reports], and the AARP; all of which have Web sites that consumers and healthcare professionals can access for information. Given that reliable information is available, perhaps it would better and less costly for the Administration to direct DHS to establish a Web site with links to information on drug safety, rather than passing legislation that would require to DHS to establish a new program that essentially duplicates what is being done by other entities.

3) Drugmakers Plans for Voluntary Disclosure on the Internet. Reuters News reported on May 16, 2005 that the pharmaceutical industry plans to launch a global website in September 2005, pooling information on ongoing and completed clinical trials. Additionally, in January 2005, drugmakers in the United States, Europe, and Japan agreed on a voluntary code to publish detailed clinical trials data. Data would be available through a single website with links to company websites and other commercial and government-sponsored websites containing information provided by firms. The voluntary code is backed by Pfizer Inc, GlaxoSmithKline Plc, Merck, AstraZeneca Plc, Novartis AG and Sanofi-Aventis SA.

4) Federal Legislation. On May 4, 2005, Congressman Hinchey introduced H.R. 2090, the Food and Drug Administration Improvement Act of 2005. This bill would: 1) establish within the FDA a Center for Postmarket Drug Safety and Effectiveness to monitor all approved drugs as well as all advertisements and promotions associated with those products; 2) prohibit the FDA from collecting fees paid by companies it regulates and instead, deposit those funds into the general fund of the Treasury; 3) empower the FDA with the authority to mandate that companies conduct post-marketing studies of FDA-approved drugs; and 4) enable the FDA to mandate changes to labels of FDA-approved products if a new risk is discovered. HR 2090 has been referred to the House Committee on Energy and Commerce.

5) Other Legislation. Two other bills dealing with drug safety and reporting requirements have been introduced this session.

SB 380 (Alquist) Drugs: Adverse Event Reporting, would require licensed health professionals and a health facilities to report serious adverse drug events that they observe to MedWatch, the FDA's drug safety information and adverse event reporting program. (MedWatch is a voluntary reporting program that allows healthcare professionals and consumers to report serious problems that they suspect are associated with the drugs and medical devices they prescribe, dispense, or use.)

SB 329 (Cedillo) California Prescription Drug Safety and Effectiveness Commission. This is a spot bill that was introduced but not heard in its first committee.

6) History.

2005	
June 23	From committee chair, with author's amendments: Amend, and re-refer to committee. Read second time, amended, and re-referred to Com. on HEALTH.
June 15	Referred to Com. on HEALTH.
June 6	In Senate. Read first time. To Com. on RLS. for assignment.
June 2	Read third time, passed, and to Senate. (Ayes 44. Noes 34. Page 2146.)
May 27	Read second time. To third reading.
May 26	From committee: Amend, and do pass as amended. (Ayes 12. Noes 5.) (May 25). Read second time and amended. Ordered returned to second reading.
April 27	In committee: Set, first hearing. Referred to APPR. suspense file.
Apr. 19	Re-referred to Com. on APPR.
Apr. 18	Read second time and amended.
Apr. 14	From committee: Amend, do pass as amended, and re-refer to Com. on APPR. (Ayes 9. Noes 4.) (April 12).
Apr. 11	Re-referred to Com. on HEALTH.
Apr. 7	From committee chair, with author's amendments: Amend, and re-refer to Com. on HEALTH. Read second time and amended.
Feb. 15	Re-referred to Com. on HEALTH.
Feb. 11	From committee chair, with author's amendments: Amend, and re-refer to Com. on HEALTH. Read second time and amended.
Jan. 18	Referred to Com. on HEALTH.
Jan. 4	From printer. May be heard in committee February 3.
Jan. 3	Read first time. To print.

AB 71

As Amended May 26, 2005

ASSEMBLY THIRD READING

Majority vote

HEALTH 9-4 APPROPRIATIONS 12-5

Ayes:	Chan, Berg, Cohn, Frommer, De La Torre, Jones, Montanez, Negrete McLeod, Ridley-Thomas	Ayes:	Chu, Bass, Berg, Mullin, Karnette, Klehs, Leno, Nation, Oropeza, Ridley-Thomas, Saldana, Yee
Nays:	Aghazarian, Nakanishi, Richman, Strickland	Nays:	Sharon Runner, Emmerson, Haynes, Nakanishi, Walters

SUMMARY : Establishes the Office of California Drug Safety Watch (Office) within the Department of Health Services (DHS) to create a central repository of information about the safety and effectiveness of prescription drugs that are frequently advertised on television. Specifically, this bill:

1)Establishes the Office of California in DHS to do all of the following:

a) Establish a central repository of information about the safety and effectiveness of prescription drugs that are frequently advertised on television;

b) Disseminate information to health care professionals and consumers through an Internet Web site which shall include links to other relevant web-based information that has been professionally reviewed and approved;

c) Ensure that the dissemination of information is done in a culturally competent manner, and that addresses the differential impact of medications within a class based on gender, age, and ethnicity, when that information is available;

d) In selecting therapeutic classes of drugs about which to develop information, choose the four most frequently advertised classes of drugs for which there is recently published systematically reviewed evidence-based research;

e) Request units of the University of California and the California State University to provide assistance; and,

f) Rely on systematically reviewed evidence-based research.

2)Requires the Office to coordinate its activities with other state departments and agencies to avoid unnecessary duplication.

3)Defines the following:

a) "Evidence-based research" means prescription drug research in which the drugs in question have been administered to experimental and control groups and the subsequent effect of the drugs has been observed through those groups; and,

b) "Systematically reviewed" means review of evidence-based research that uses rigorous, unbiased methods to examine the similarities and differences of results across many individual research studies. The goal of a systematic review is to estimate the comparative effectiveness and safety of healthcare treatments. A systematic approach to reviewing the evidence increases the reliability of the results, and the transparency of the procedures.

c) "Most frequently advertised classes of drugs" means the therapeutic classes of drugs most frequently advertised on television for the six-month period immediately prior to the date the Office begins compiling the drug safety and effectiveness information required by this bill. Frequently advertised classes of drugs shall not include any therapeutic class that is used primarily to treat mental illness.

EXISTING LAW :

1)Regulates the packaging, labeling and advertising of food, drugs, and cosmetics under the administration of DHS.

2)Creates in the federal government the Food and Drug Administration (FDA) to regulate prescription drugs.

FISCAL EFFECT : According to the Assembly Appropriations Committee:

1)On-going annual General Fund (GF) personnel costs of $240,000 for staff in the Office.

2)GF costs of approximately $205,000 for the acquisition of journal articles, translation, and field testing of translated

materials in a culturally competent manner.

COMMENTS : To highlight the importance of this bill, the author points to the withdrawal of Vioxx and Celebrex in November and December 2004 from the market because of the risks of heart attack associated with taking these drugs. On April 7, 2005, FDA asked Pfizer to withdraw Bextra from the market because it increases the risk of heart attacks, stroke and skin reactions. Like Vioxx and Celebrex, Bextra is a cox-2 inhibitor. These events created great insecurities among consumers. The author points out that if there is a single repository of information for the safety and effectiveness of drugs, consumers would have more information on the safety and effectiveness of prescription drugs they are taking and would be encouraged to discuss such information with their physicians.

The pull-out of Vioxx and Celebrex and most recently Bextra from the market because of adverse drug reactions has changed the landscape on how consumers view drugs and associated risks. A 2005 Kaiser Family Foundation survey found that 66% of adults closely followed news stories about Vioxx and Celebrex in December 2004 and a large majority (80%) felt "somewhat" confident about the safety of prescription drugs sold in the United States. The same survey indicated that a vast majority of adults (90%) have seen or heard advertisements for prescription drugs but only 18% of consumers now believe pharmaceutical ads can be trusted "most of the time." This is a significant drop because in 1997 one-third of those surveyed indicated ads could be trusted most of the time. The importance of these drug advertisements to delivering the safety or risks of drugs has caught the attention of FDA when it announced that it would be more aggressive in monitoring drug advertisements so as to balance the presentation of the benefits and risks of particular drugs.

Supporters indicate that prescription drug safety is a serious concern among Californians. Peer-reviewed and scientifically based studies would provide additional and valuable information to physicians, surgeons and patients. The California Medical Association in support notes the importance of this information while emphasizing the need for patients to consult their physicians before discontinuing any prescribed medications.

Letters received in opposition appear to address the February 11, 2005, version of this bill, which would have required DHS to establish a toll-free telephone number to receive reports of adverse drug reactions, establish a Web site with adverse drug reaction information, maintain a database and act as a liaison with the FDA. Opponents claim that FDA's Medwatch, which allows reporting of adverse drug reactions, provides sufficient protection to the public. It is unclear whether they are still

opposed to this bill in its most recently amended form.

Analysis Prepared by: Rosielyn Pulmano / HEALTH / (916) 319-2097

AMENDED IN ASSEMBLY JUNE 21, 2005

AMENDED IN SENATE APRIL 28, 2005

AMENDED IN SENATE APRIL 11, 2005

SENATE BILL No. 380

Introduced by Senator Alquist

February 17, 2005

An act to add Article 7 (commencing with Section 111657) to Chapter 6 of Part 5 of Division 104 of the Health and Safety Code, relating to drugs.

LEGISLATIVE COUNSEL'S DIGEST

SB 380, as amended, Alquist. Drugs: adverse event reporting.

The Sherman Food, Drug and Cosmetics Law provides for the regulation of various subjects relating to the processing, labeling, advertising, and sale of food, drugs, and cosmetics under the administration of the State Department of Health Services. A violation of these provisions is a crime.

This bill would require a licensed health professional and a health facility to report all suspected serious adverse drug events that are spontaneously discovered or observed in medical practice to MedWatch, the drug safety information and adverse event reporting program operated by the federal Food and Drug Administration (FDA), using the FDA 3500 Voluntary form developed by the FDA for MedWatch. The bill would prohibit a licensed health professional or health facility that violates this provision from being subject to the existing penalties and remedies of the Sherman Food, Drug and Cosmetics Law or any other provision of law.

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

The people of the State of California do enact as follows:

SECTION 1. The Legislature finds and declares all of the following:

(a) The federal Food and Drug Administration (FDA) operates a voluntary reporting system for adverse drug reactions known as the MedWatch system.

(b) The FDA currently estimates that only 10 percent of the adverse drug reactions or events that occur each year are reported to the FDA.

(c) Given the prevalence of pharmaceuticals and their use for treatment of hundreds of chronic diseases and conditions, and given recent highly publicized instances of commonly used prescription drugs being taken off the market due to safety concerns that were discovered after the drugs were approved for use, the systematic underreporting of adverse drug events represents a serious public health problem.

(d) Requiring licensed health professionals of organizations to report adverse drug events to the FDA would increase the amount of data available to the FDA about adverse drug reactions, thereby enabling the FDA to discern problems with drugs that arise after they are approved and to take action to protect the public health in a more timely manner.

SEC. 2. Article 7 (commencing with Section 111657) is added to Chapter 6 of Part 5 of Division 104 of the Health and Safety Code, to read:

Article 7. Adverse Event Reporting

111657. (a) A licensed health professional, including, but not limited to, a physician and surgeon, dentist, or pharmacist, and a health facility, including, but not limited to, a hospital or clinic, shall report all suspected serious adverse drug events that are spontaneously discovered or observed in medical practice to MedWatch, the drug safety information and adverse event reporting program operated by the federal Food and Drug Administration.

(b) For purposes of this section, serious adverse drug events shall include adverse health outcomes involving patients that result in death, life-threatening conditions, hospitalization,

disability, congenital anomaly, or required intervention to prevent permanent impairment or damage.

(c) Any health professional or health facility that is required to report an adverse drug event pursuant to this section shall do so using the FDA 3500 Voluntary form developed by the federal Food and Drug Administration for MedWatch.

111658. A licensed health professional or health facility that violates any provision of this article shall not be subject to the penalties and remedies outlined in Chapter 8 (commencing with Section 111825) or any other provision of law. *Nothing in this section affects otherwise existing duties, rights, or remedies under the law.*

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CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: SB 380 **VERSION: AMENDED APRIL 28, 2005**

AUTHOR: ALQUIST **SPONSOR: SENIOR CITIZENS, SO. CAL**

RECOMMENDED POSITION: NO POSITION

SUBJECT: DRUGS: ADVERSE EVENT REPORTING

Existing Law:

The Federal Food, Drug, and Cosmetic Act and the Modernization Act establish the Food and Drug Administration's (FDA) postmarketing and risk assessment programs for adverse drug reactions. The laws also establish mandatory reporting requirements for drug manufactures to report adverse drug reactions.

This Bill:

1) Requires a licensed health professional, (a physician and surgeon, dentist, or pharmacist), and a health facility, (a hospital or clinic), to report all suspected serious adverse drug events that are spontaneous or observed in medical practice to the FDA's MedWatch program.

2) Requires the report to be made using FDA 3500, Voluntary form.

3) Defines a serious adverse drug events as, adverse health outcomes involving patients that result in death, life-threatening conditions, hospitalization, disability, congenital anomaly, or required intervention to prevent permanent impairment or damage.

4) Provides that a person or health facility that violates any provision of the measure would not be subject to penalties and remedies in H&S 111825 or any other provisions in law. (Penalties under H&S 111825 are imprisonment for not more than one year in the county jail or a fine of not more than $1,000, or both the imprisonment and fine.)

(H&S 111657 Added)

Comment:

1) Author's Intent. The author is concerned that the FDA may not be receiving enough information about adverse drug reactions to make informed decisions to protect the public health.

2) Enforcement. This bill lacks language that would make the bill enforceable. There is no way to know how many adverse drug reactions a health professional observes each year. Consequently this bill would be impossible to enforce. Additionally, it is unclear how each regulatory board would know that an event should have been reported, but wasn't.

3) FDA's MedWatch Program. MedWatch is a voluntary reporting program run by the FDA that allows healthcare professionals and consumers to report serious problems that they suspect are associated with the drugs and medical devices they prescribe, dispense, or use.

Reporting is done on line, by phone, or by submitting the MedWatch 3500 form by mail or fax. The FDA disseminates medical product safety alerts, recalls, withdrawals, and important labeling changes to the medical community and the general public via its web site and the Med Watch E-list.

4) Drugmakers Plans for Voluntary Disclosure on the Internet. Reuters News reported on May 16, 2005 that the pharmaceutical industry plans to launch a global website in September 2005, pooling information on ongoing and completed clinical trials. Additionally, in January 2005, drugmakers in the United States, Europe, and Japan agreed on a voluntary code to publish detailed clinical trials data. Data would be available through a single website with links to company websites and other commercial and government-sponsored websites containing information provided by firms. The voluntary code is backed by Pfizer Inc, GlaxoSmithKline Plc, Merck, AstraZeneca Plc, Novartis AG and Sanofi-Aventis SA.

5) Other Legislation. Two other bills dealing with drug safety and reporting requirements have been introduced this session.

AB 71 (Chan) Office of California Drug Safety Watch, would require DHS to 1) establish a central repository of information about the safety and effectiveness of prescription drugs; and 2) disseminate information to health care professionals and consumers through a Web site that would include links to other relevant web-based information that has been professionally reviewed and approved.

SB 329 (Cedillo) California Prescription Drug Safety and Effectiveness Commission. This is a spot bill and will be amended for other purposes.

6) Federal Legislation. On May 4, 2005, Congressman Hinchey introduced H.R. 2090, the Food and Drug Administration Improvement Act of 2005. This bill would: 1) establish within the FDA a Center for Postmarket Drug Safety and Effectiveness to monitor all approved drugs as well as all advertisements and promotions associated with those products; 2) prohibit the FDA from collecting fees paid by companies it regulates and instead, deposit those funds into the general fund of the Treasury; 3) empower the FDA with the authority to mandate that companies conduct post-marketing studies of FDA-approved drugs; and 4) enable the FDA to mandate changes to labels of FDA-approved products if a new risk is discovered. HR 2090 has been referred to the House Committee on Energy and Commerce.

7) Support & Opposition.

Support: American Federation of State, County and Municipal Employees
California Alliance for Retired Americans
California Labor Federation
California Psychological Association
California Public Interest Research Group
Congress of California Seniors
Consumers Union
Greenlining Institute
Health Access California
Protection and Advocacy, Inc.

Opposition: American College of Obstetricians and Gynecologists, Region IX
California Hospital Association
California Medical Association
California Society of Health-System Pharmacists
Kaiser Permanente

8) History.

2005

June 29	From committee: Do pass, but first be re-referred to Com. on APPR. (Ayes 7. Noes 0.) Re-referred to Com. on APPR.
June 21	From committee with author's amendments. Read second time. Amended. Re-referred to committee.
June 15	From committee: Do pass, but first be re-referred to Com. on B. & P. (Ayes 9. Noes 4.) Re-referred to Com. on B. & P.
June 7	Set, first hearing. Hearing canceled at the request of author.
May 26	To Coms. on HEALTH and B. & P.
May 2	In Assembly. Read first time. Held at Desk.
May 2	Read third time. Passed. (Ayes 23. Noes 13. Page 867.) To Assembly.
Apr. 28	Read second time. Amended. To third reading.
Apr. 27	From committee: Do pass as amended. (Ayes 9. Noes 2. Page 767.)
Apr. 18	Set for hearing April 25.
Apr. 11	Read second time. Amended. Re-referred to Com. on APPR.
Apr. 7	From committee: Do pass as amended, but first amend, and re-refer to Com. on APPR. (Ayes 7. Noes 3. Page 411.)
Mar. 14	Set for hearing March 30.
Feb. 24	To Com. on HEALTH.
Feb. 18	From print. May be acted upon on or after March 20.
Feb. 17	Introduced. Read first time. To Com. on RLS. for assignment. To print.

SB 380

As Amended: June 21, 2005

ASSEMBLY COMMITTEE ON BUSINESS AND PROFESSIONS
Gloria Negrete McLeod, Chair
SB 380 (Alquist) -

SENATE VOTE : 23-13

SUBJECT : Drugs: adverse event reporting.

SUMMARY : Requires health care providers to report suspicious serious adverse drug events to the federal Food and Drug Administration (FDA) Specifically, this bill :

1)Requires licensed health professionals and health facilities to report all suspected serious adverse drug events that are spontaneously discovered or observed in medical practice to MedWatch, the drug safety information and adverse event reporting program operated by the FDA. Requires such reports to be done using Form FDA 3500 for voluntary reporting.

2)Defines serious adverse drug events, for purposes of this bill, to mean adverse health outcomes involving patients that result in death, life-threatening conditions, hospitalization, disability, congenital anomaly, or required intervention to prevent permanent impairment or damage.

3)Prohibits a licensed health professional or health facility that violates this bill from being subject to the penalties and remedies of the Sherman Food, Drug and Cosmetics Law (Sherman Law) or any other provision of law.

EXISTING LAW :

1)Establishes the Sherman Law, which provides for the regulation of food, drugs and cosmetics under the administration of the Department of Health Services (DHS). Makes a violation of the Sherman Law a crime.

2)Establishes, under federal law, the MedWatch program as a voluntary safety and adverse event reporting system, administered by FDA.

FISCAL EFFECT : Unknown. According to the Senate Appropriations Committee analysis, $100,000 over two budget years for notification of health care professionals and health facilities about this new requirement and for DHS to investigate a few reporting incidents to see if the appropriate reports are being filed.

COMMENTS :

Purpose of this bill . According to the author, this bill is needed to increase the reporting of adverse drug reactions. Currently, health professionals are only required to report adverse drug reactions on a voluntary basis. The author reports that this results in reporting of only a small percent of the adverse drug reactions that occur. Based on the prevalence of prescription drug use and the recent recall of frequently used drugs, the author believes that under-reporting of adverse reactions is a serious public health problem. The author reports that adverse drug events or reactions (ADRs) result in more than 2.1 million injuries each year and states that studies reported in the Journal of the American Medical Association (JAMA) found that 100,000 Americans die annually of adverse reactions to prescription drugs and that the risk of death for a patient who experiences an ADR is estimated to be nearly twice that of a patient who does not.

Background . With the use of any medication comes the possibility of unintended consequences. These events, when harmful, are often referred to ADRs. According to a 1997 JAMA article, "Adverse Drug Reactions in Hospitalized Patients," an estimated 770,000 people are injured or die each year in hospitals from ADRs. A separate report estimates that ADRs are responsible for up to 140,000 injuries or death in the United States each year. According to the FDA, the estimated cost of morbidity and mortality related to ADRs is more than $75 billion annually, and ADRs are among the top 10 leading causes of death.

Premarketing trials of drugs frequently do not have a large enough sample of drug recipients to reliably detect important ADRs, which may only occur at the rates of 1 in 10,000 or fewer drug exposures. Premarketing trials also lack the follow-up necessary to detect ADRs widely separated in time from the original use of the drug or delayed consequences associated with long-term drug administration. Taken together, these limitations of premarketing clinical trials mean that FDA approval of a new drug does not exclude the possibility of rare but serious ADRs or common, delayed ADRs. A number of methods have been used to identify previously unknown detrimental outcomes that may be attributable to the use of medications, including post approval spontaneous case reports.

According to an article, "Postmarketing Surveillance and Adverse Drug Reactions," reported in JAMA in 1999, more serious ADRs have been noted first in case reports than any other detection method. One such case reporting system is the MedWatch program that was introduced by the FDA in 1993 to improve the detection of previous unknown serious ADRs. Under MedWatch, health care

professionals are encouraged to voluntarily report serious events suspected to be caused by medications, medical devices, special nutritional products, and other products regulated by the FDA. Serious events are those that result in death, life-threatening conditions, hospitalization, disability, congenital anomaly, or required intervention to prevent permanent impairment or damage. (This bill uses the same definition of serious events.) Physicians may report ADRs by telephone, fax, or mail or through the Internet. Despite the importance of physician reports for detecting ADRs, serious adverse events that may represent ADRs are vastly underreported by physicians to either manufacturers or the FDA. According to the FDA, the extent of underreporting is unknown with researchers estimating that as few as less than 1%, to as many any 8-13%, of ADRs being reported. Currently, the FDA receives approximately 250,000 voluntary MedWatch reports annually.

The FDA also has a mandatory ADR reporting process for drug manufacturers who are required to report to the FDA any suspected ADR reports within 15 days of receipt of such a report. In addition, user-facilities such as hospitals and nursing homes are legally required to report suspected medical device-related deaths to both FDA and the manufacturer, if known, and serious injuries to the manufacturer or to FDA, if the manufacturer is unknown.

Support . Supporters argue that this bill protects the health of California consumers by improving the detection of serious side effects of medications that have reached the market. Supporters believe that voluntary reporting of ADRs is inadequate and that mandatory reporting should be required. Supporters point to multiple recalls of medications that have taken place only after many Americans have suffered injury or death from their side effects. Mandatory reporting would provide an earlier warning to the FDA about potentially harmful drugs and allow warning labels or removal from the market to occur sooner, before more people have been harmed. Consumers Union argues that FDA officials have reported that the lack of adequate reporting of adverse drug reactions inhibits the agency's ability to identify dangerous drugs.

Opposition . Opponents argue that this bill would not improve the delivery of health care, that it is often impossible to narrow the cause of an adverse event to a reportable issue, and that virtually all adverse drug events will result in an intervention to prevent permanent impairment or damage. Opponents support continued voluntary, rather than mandatory, reporting.

Related legislation . AB 71 (Chan) would establish the Office of California Drug Safety Watch within DHS to create a central

repository of information about the safety and effectiveness of prescription drugs that are frequently advertised on television. AB 71 passed the Assembly and is pending in the Senate.

Questions and comments . Will the requirement to report serious ADRs result in increased reporting given that this bill prevents the imposition of any penalties for failure to report? Should this bill have a sunset date, allowing its repeal if it fails to significantly increase reporting or otherwise fails to accomplish the author's goal?

REGISTERED SUPPORT / OPPOSITION :

Support

American Federation of State, County and Municipal Employees
California Alliance for Retired Americans
California Labor Federation
California Psychological Association
California Public Interest Research Group
Congress of California Seniors
Consumers Union
Greenlining Institute
Health Access California
Protection and Advocacy, Inc.

Opposition

American College of Obstetricians and Gynecologists, Region IX
California Dental Association
California Hospital Association
California Medical Association
California Society of Health-System Pharmacists
Kaiser Permanente

Analysis Prepared by : Ross Warren / B. & P. / (916) 319-3301

AMENDED IN ASSEMBLY MAY 26, 2005

AMENDED IN ASSEMBLY APRIL 4, 2005

CALIFORNIA LEGISLATURE—2005–06 REGULAR SESSION

ASSEMBLY BILL No. 72

Introduced by Assembly Members Frommer and Chan (Coauthors: Assembly Members Bass, Evans, Gordon, Koretz, Nava, Pavley, and Salinas)

January 3, 2005

An act to add Chapter 9 (commencing with Section 119500) to Part 15 of Division 104 of the Health and Safety Code, relating to prescription drug trials.

LEGISLATIVE COUNSEL'S DIGEST

AB 72, as amended, Frommer. Prescription drugs: clinical trials.

Existing law regulates the labeling, sale, and use of prescription drugs and devices.

This bill would establish the Patient Safety and Drug Review Transparency Act in order to ~~assure~~ *ensure* that information regarding clinical trials of prescription drugs is available to the public, physicians, and researchers. The bill would prohibit an institutional review board with responsibility for ensuring the protection of the rights, safety, and well-being of human subjects involved in clinical trials of prescription drugs from approving any clinical trial related to a prescription drug unless the sponsor certifies in writing that it (1) will register the clinical trial, no later than 21 days after ~~it begins~~ *its approval by the institutional review board*, with a government sponsored and public clinical trial registry, (2) will publish the results of the study, and (3) has complied with the registry and publication

requirements for any prior ~~study~~ *clinical trial* that was approved by the board.

~~This bill would prohibit the board from approving any study related to a prescription drug if the sponsor failed during a prior study that was approved by the board to comply with the above requirements. Prior to approval, the bill would require the board to review whether the sponsor, in prior approved studies, actually complied with those requirements.~~

The bill would provide that any sponsor who does not comply with the requirements it certified in writing is liable for a civil penalty of $1,000 per violation. The bill would authorize the Attorney General, a district attorney, or city attorney to bring an action against a sponsor to ~~recover civil penalties~~ *enforce compliance with its requirements*.

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

The people of the State of California do enact as follows:

SECTION 1. Chapter 9 (commencing with Section 119500) is added to Part 15 of Division 104 of the Health and Safety Code, to read:

CHAPTER 9. ~~INFORMATION REQUIRED FOR DRUG STUDIES~~
PATIENT SAFETY AND DRUG REVIEW TRANSPARENCY

119500. (a) This chapter may be referred to as the "Patient Safety and Drug Review Transparency Act."

(b) The purpose of this act is to ~~assure~~ *ensure* that information regarding clinical trials of prescription drugs is available to the public, physicians, and researchers. Making information about drug trials and their results available in a national, publicly accessible database will improve the safety of human subjects and provide all citizens of this state with complete safety information about the prescription drugs they take.

(c) For purposes of this chapter, the following terms have the following meanings:

(1) "Clinical trial" means a *Phase 2, 3, or 4* clinical investigation as defined by the federal Food and Drug Administration ~~that involves any experiment~~ to test the safety or efficacy of a drug or biological product with one or more human

subjects and is intended to be submitted to, or held for inspection by, the federal Food and Drug Administration as part of an application for a research or marketing permit.

(2) "Clinical trial registry" means a publicly available ~~databank~~ *database* established by the National Library of Medicine pursuant to 42 U.S.C. Section 282 (j).

(3) "Institutional review board" means an independent body constituted of medical, scientific, and nonscientific members, whose responsibility is to ensure the protection of the rights, safety, and well-being of human subjects involved in clinical trials of prescription drugs by, among other things, reviewing, approving, and providing continuing review of trial protocol and the methods and material to be used in obtaining and documenting informed consent of the trial subjects. *The institutional review board is constituted under Subtitle A (commencing with Section 46.101) of Part 46 of Title 45 of the Code of Federal Regulations, to review and monitor research involving human subjects.*

(4) "Sponsor" means the manufacturer, or if the manufacturer provides no monetary support for the trial, the person who provides the majority of monetary support, or, where the majority funder is a state or federal agency, the principal investigator.

~~(d) An institutional review board shall not approve any clinical trial related to a prescription drug unless the sponsor certifies in writing that it has done or will do all of the following:~~

(d) A sponsor of a clinical investigation shall certify to the relevant institutional review board and to the Attorney General that the sponsor has done or will do all of the following:

(1) Register the clinical trial, no later than 21 days after ~~it begins, by providing information necessary for publication in a government-sponsored~~ *approval of the clinical trial by the institutional review board, by providing information necessary for publication in a government-sponsored* and public clinical trial registry in the manner required by regulations or other guidance established by the National Library of Medicine or the United States Secretary of Health and Human Services.

(2) Publish the ~~results of the study by providing the results of the study for publication~~ *summary results of the trial, whether positive or negative,* in a government sponsored and public clinical trial registry, in a manner required by regulations or other

guidance established by the National Library of Medicine or the United States Secretary of Health and Human Services, *in a peer-reviewed medical journal,* or in another publicly accessible database.

(3) Complied with the provisions of paragraphs (1) and (2) for any prior ~~study~~ *clinical trial* that was approved by the board pursuant to this chapter.

~~(e) An institutional review board shall not approve any study related to a prescription drug if the sponsor failed during a prior study that was approved by the board pursuant to this chapter to comply with the requirements it certified in writing under subdivision (d). Prior to approval, the board shall review whether the sponsor, in prior studies approved pursuant to this chapter, actually complied with those requirements.~~

~~(f) Any sponsor who does not comply with the requirements it certified in writing under subdivision (d) shall be liable for a civil penalty of one thousand dollars ($1,000) per violation payable to the general fund of the entity bringing the action. Each day a sponsor is in violation shall be considered a separate violation. The Attorney General, a district attorney, or city attorney may bring an action against a sponsor to recover civil penalties for not complying with the requirements the sponsor certified in writing under subdivision (d).~~

(e) Any sponsor who does not comply with the requirements of this chapter within 30 days after receipt of written notice from the Attorney General, a district attorney, or a city attorney shall be liable for a civil penalty of one thousand dollars ($1,000) per violation payable to the general fund of the entity bringing the action. Each day a sponsor remains in violation of this chapter after the conclusion of the 30-day period shall be considered a separate violation. The Attorney General, a district attorney, or a city attorney may bring an action against a sponsor to enforce compliance with the requirements of this chapter.

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CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: AB 72 **VERSION: AMENDED MAY 26, 2005**

AUTHOR: FROMMER et. al. **SPONSOR: FROMMER**

RECOMMENDED POSITION: NO POSITION

SUBJECT: CLINICAL TRIALS

Existing Law:

The Federal Food, Drug, and Cosmetic Act and the Modernization Act establishes the Food and Drug Administration's (FDA) postmarketing and risk assessment programs for adverse drug reactions. The laws also establish mandatory reporting requirements for drug manufacturers to report adverse drug reactions.

This Bill:

1) Establishes the Patient Safety and Drug Review Transparency Act.

2) Defines the terms: "Clinical trial", "Clinical trial registry", "Institutional review board", and "Sponsor."

3) Requires a sponsor of a clinical investigation to certify to the relevant institutional review board and to the Attorney General that the sponsor has done or will do all of the following:

a. Register the clinical trial, no later than 21 days after approval of the clinical trial by the institutional review board, by providing information necessary for publication in a government-sponsored and public clinical trial registry in the manner required by regulations or other guidance established by the National Library of Medicine or the United States Secretary of Health and Human Services.

b. Publish the summary results of the trial, whether positive or negative, in a government sponsored and public clinical trial registry, or other publicly accessible database.

c. Complied with the provisions of the measure for any prior clinical trial that was approved by the board.

5) Establishes a civil penalty of $1,000 per violation for any sponsor who does not comply with provisions of the bill. Each day a sponsor is in violation would be considered a separate violation.

(H&S 119500 Added)

Comment:

1) Author's Intent. The author's intent is to assure that information regarding clinical trials of prescription drugs is available to the public, physicians, and researchers.

2) History.

2005

June 2	Action rescinded and record expunged whereby the bill was read third time and whereby a final roll call vote was taken. To inactive file on motion of Assembly Member Frommer
May 27	Read second time. To third reading.
May 26	From committee: Amend, and do pass as amended. (Ayes 11. Noes 5.) (May 25). Read second time and amended. Ordered returned to second reading.
May 11	In committee: Set, first hearing. Referred to APPR. suspense file.
Apr. 13	From committee: Do pass, and re-refer to Com. on APPR. Re-referred. (Ayes 10. Noes 3.) (April 12).
Apr. 5	Re-referred to Com. on HEALTH.
Apr. 4	From committee chair, with author's amendments: Amend, and re-refer to Com. on HEALTH. Read second time and amended.
Jan. 18	Referred to Coms. on HEALTH and JUD.
Jan. 4	From printer. May be heard in committee February 3.
Jan. 3	Read first time. To print.

AB 72

As Amended May 26, 2005

ASSEMBLY THIRD READING

Majority vote

HEALTH 10-3 APPROPRIATIONS 11-5

Ayes:	Chan, Berg, Cohn, Dymally, Frommer, De La Torre, Jones, Montanez, Negrete McLeod, Ridley-Thomas	Ayes:	Chu, Bass, Berg, Karnette, Klehs, Leno, Nation, Oropeza, Ridley-Thomas, Saldana, Yee
Nays:	Aghazarian, Nakanishi, Strickland	Nays:	Sharon Runner, Emmerson, Haynes, Nakanishi, Walters

SUMMARY : Requires sponsors of clinical trials to certify that they have registered the clinical trials and that they will publish the results of the trial, whether positive or negative, as specified. Specifically, this bill :

1)Requires a sponsor of a clinical investigation to certify to the relevant institutional review board (IRB) and to the Attorney General (AG) that the sponsor has done or will do all of the following:

a) Register the clinical trial, no later than 21 days after approval of the clinical trial by IRB by providing information necessary for publication in a government sponsored and public clinical trial registry in the manner required by regulations or other guidance established by the National Library of Medicine or the United States Department of Health and Human Services (USHHS);

b) Publish the summary results of the trial, whether positive or negative, in a government sponsored and public clinical trial registry, in a manner required by regulations or other guidance established by the National Library of Medicine or the USHHS, in a peer-reviewed medical journal or in another publicly accessible database; and,

c) Comply with the provisions of a) and b), above, for any prior clinical trial that was approved by IRB pursuant to

this bill.

2)Makes a sponsor who does not comply with the requirements of this bill within 30 days receipt of written notice, as specified, liable for a civil penalty of $1,000 per violation. Makes each day a sponsor remains in violation of this bill after the conclusion of the 30-day period a separate violation. Permits the AG, a city attorney, or a district attorney to enforce compliance with the provisions of this bill.

3)Defines, for the purpose of this bill, the following terms: clinical trial, clinical trial registry, institutional review board, and sponsor.

FISCAL EFFECT : According to the Assembly Appropriations Committee, General Fund costs of approximately $150,000 to the Department of Justice (DOJ) to administer and enforce the provisions of this bill.

COMMENTS : According to the author, this bill would improve the safety of prescription drugs by ensuring that patients, physicians, and researchers could access information about the clinical trials that test the safety and effectiveness of those drugs. The author states that federal law dealing with clinical trials fails to require registration of all trials, does not penalize companies that fail to register their trials and does not mandate the publication of the results of these trials. The author believes that this bill will not only improve patient care, but could also reduce health care costs. According to the author, research has shown that publication bias (that is, that studies showing positive results are more likely to be published than studies showing negative results) leads to a bias toward new and more expensive treatment options. A clinical trial registry can help patients and doctors understand that in some cases less expensive treatment may be just as effective. Although federal legislation has been introduced to address some of these shortcomings, the author states that Congress shows little willingness to ensure that the public gets the information it needs about clinical trials. As a result, states must step in with legislation such as this bill.

Current state law does not require the registration of a clinical trial or the publication of the results of a trial. Congress, in the Food and Drug Administration Modernization Act (FDAMA) of 1997, required USHHS to establish a publicly accessible data bank of information about clinical trials for serious or life threatening diseases and conditions. FDAMA also requires the sponsors of investigational new drug applications to submit to the data bank a description of the purpose of each experimental drug, eligibility criteria for participation in the

trial, the location of clinical trial sites and a point of contact for people interested in enrolling in the trial.

To implement this law, the National Institutes of Health, through its National Library of Medicine, and the Food and Drug Administration (FDA) developed the ClinicalTrials.gov Web site in 2000 to serve as the data bank for clinical trial information. Despite the best efforts by FDA to inform drug manufacturers and drug trial sponsors of the FDAMA registration requirements, an FDA review published in 2004 found that:

1)Some pharmaceutical companies are not providing adequate information about their trials, for example, some trials are listed without identifying the sponsoring company or the drug being tested.
2)Some companies listed no trials and some listed only a few that follow FDA guidelines,
3)Only 48% of mandated industry-sponsored and 91% of mandated NIH cancer-related trials were registered.
4)For non-cancer trials, participation appeared to be in the single-digit range for some serious disease categories.

In June 2004, the American Medical Association (AMA) recommended that HHS create a comprehensive, centralized clinical trials registry. In 2004 the International Committee of Medical Journal Editors (ICMJE) published an editorial in the New England Journal of Medicine stating that ICMJE member journals will require, as a condition of consideration for publication, registration of the clinical trials being reported on in a public trials registry such as ClinicalTrials.gov, effective for any trial starting enrollment after July 1, 2005. The Congressional Research Service reports that the pharmaceutical industry's reaction to clinical trials reporting has been mixed, although as litigation and FDA and congressional interest have increased, some individual manufacturers and groups have volunteered to make some of their clinical trials data public.

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