AMENDED IN SENATE MARCH 31, 2009

SENATE BILL No. 341

Introduced by Senator DeSaulnier

February 25, 2009

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

SB 341, as amended, DeSaulnier. Pharmaceuticals: adverse drug reactions: Drug Safety and Effectiveness Program.

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 Public Health.

This bill would require the department to make every effort to enter into a contract or agreement with the University of California to establish a program to evaluate the safety and effectiveness of prescription drugs in California. This bill would require, if the department and the University of California enter into a contract or agreement to establish the program, that the program include specified components, including, among other things, a determination of the classes of prescription drugs that are advertised to consumers, marketed to physicians, or both, in California, and an Internet Web site designed to disseminate information to health care professionals and consumers on the relative safety and effectiveness of those drugs, as specified. *The program shall include, until January 1, 2015, a prescription education service, as specified.*

This bill would impose a fee, to be established by the department, on any manufacturer of drugs to which the bill applies, in an amount determined by the department, in consultation with the University of

California, and limited to the amount necessary to fund the actual and necessary expenses of the University of California in implementing the program. This bill would require the fee to be collected by the State Board of Equalization, and to be deposited into the Drug Safety and Effectiveness Fund, which would be created by the bill, and used, upon appropriation by the Legislature, for purposes of the bill.

This bill would specify that the provisions relating to the establishment and the collection of this fee shall not be implemented until the department and the University of California enter into a contract or agreement, as provided for in the bill.

The bill would require the department to provide an annual report on the service to specified legislative committees.

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. The Legislature finds and declares all of the following:

(a) Since 1997, when the United States Food and Drug Administration (FDA) allowed drug manufacturers to advertise directly to consumers, the amount spent on advertising has risen dramatically.

(b) According to the United States General Accounting Office (GAO) report, the pharmaceutical industry spent $2.7 billion in 2001 on direct-to-consumer advertising. A December 6, 2004, New York Times report states that such spending has reached $3.8 billion.

(c) According to the same GAO report, while overall spending on drug promotion was less than spending on research and development ($19.1 billion versus $30.3 billion), spending on direct-to-consumer advertising is increasing at a faster rate than overall drug promotion spending or spending on research and development. Between 1997 and 2001, the increase in direct-to-consumer advertising was 145 percent compared to a 59 percent increase for research and development.

(d) Although the FDA is responsible for postmarket surveillance of prescription drugs, numerous concerns have been 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.

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

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

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

(*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. Drug Safety and Effectiveness Program

111657. (a) The State Department of Public Health shall make every effort to enter into a contract or agreement with the University of California to establish a program to evaluate scientific literature that the University of California, if it enters into the agreement or contract with the department, determines relevant to the safety and effectiveness of prescription drugs in the state.

(b) The program shall have all of the following components:

(1) A determination of the classes of prescription drugs that are advertised to consumers, marketed to physicians, or both, in the state.

(2) (A) An Internet Web site that will report information on the safety and effectiveness of brand name and generic drugs in the classes that are identified pursuant to paragraph (1), including, when available, direct comparisons of relative safety and effectiveness, and differential safety and effectiveness of specific drugs according to age, gender, race, or ethnicity.

(B) This Web site shall be designed to disseminate information to health care professionals and consumers in the state, and may include links to other relevant Web-based information, if that information has been reviewed and approved by the University of California. The Internet Web site shall include the following statement: "Many factors enter into selecting the proper drug for individual patients, and different patients may respond differently to medications. The information in those reports aims to promote dialogue and responsible consumer choice. Before changing any medication, a patient should consult with his or her treating physician or other prescriber." The statement may be supplemented by any other advisory statements, as are deemed appropriate by the University of California.

(C) The Web site design shall ensure that the dissemination of information is done in a culturally competent manner. The information disseminated shall address the differential impact of medications within a class based on gender, age, race and ethnicity, and other factors when that information becomes available. Where studies are relied upon, the demographics of the individuals studied shall be included in the information disseminated.

(3) (A) A prescription education service to provide health care professionals who are licensed to prescribe or dispense

prescription drugs with information and education on the comparative efficacy, safety, and cost-effectiveness of commonly used prescription drugs and on the use of the Internet Web site established pursuant to paragraph (2).

(B) The prescription education service shall conduct in-person outreach and education sessions with health care professionals in their place of work. The sessions shall be facilitated by qualified and appropriately trained clinician educators and shall be conducted on a one-to-one basis, whenever practicable. This service shall be made available until January 1, 2015, as a pilot project in Contra Costa County to health care professionals who participate in, contract with, or are reimbursed by, state-funded health care programs. The department shall determine a second county in which the prescription education service shall be established until January 1, 2015.

(C) The department shall adopt regulations that establish all of the following:

(i) Minimum clinical and educational qualifications for prescriber and dispenser educators employed by or under contract with the service.

(ii) Required training for educators.

(iii) A code of conduct that governs the behavior of educators in their interactions with health care professionals and that establishes conflict of interest guidelines for educators and others involved in advising, developing, and administering the service.

(c) In implementing this article, any contract or agreement between the department and the University of California entered into pursuant to this section shall rely on the best scientific information that is available, as determined by the University of California, in consultation with the clinical advisory panel, giving due consideration to the diversity of the population of the State of California. When compiling evidence, any contract or agreement between the department and the University of California entered into pursuant to this section shall do all of the following:

(1) Employ a methodology that is transparent, publicly available, and open and responsive to public comment.

(2) Fully disclose its methodology, findings, and limitations.

(3) Acknowledge that no conclusion can be drawn about effectiveness if sufficient evidence is not available.

(4) Have the evidence reviewed by specialists qualified to review medical literature.

(5) Consider good quality peer-reviewed clinical trials and observational studies that provide research evidence on the comparative effectiveness, safety, and effect on subpopulations of prescription drugs, and good quality studies that link patient adherence, compliance, and tolerance and alternatives to drug therapy, such as surgery, diet, and exercise, to improved health outcomes.

(6) Consider good quality peer-reviewed research evidence that documents variations among individuals of differing age, gender, race, and ethnic subpopulations, the effect of comorbidities and co-occurring disorders, and different patient outcomes based on adherence, compliance, and tolerance.

(7) Report any identified gaps in research and opportunities to improve on currently available research.

(8) Provide a 30-day comment period during which the public, including manufacturers, providers, and payers, can provide feedback, including additional information and studies that might have been overlooked. The 30-day comment period shall be followed by a revision period before the posting of any final reviews on the Internet Web site.

(d) Any contract or agreement entered into between the department and the University of California pursuant to this section shall require the establishment of a clinical advisory panel that includes physician specialists in the drug class being reviewed, physicians and pharmacists serving diverse communities, and patient advocates, including representatives of voluntary health organizations, and senior citizen organizations to serve as advisers to the program at various stages in the process of compiling and disseminating information.

(e) The program created by this article shall not include an evaluation of any drug that is used primarily to treat mental illness, except that, where the drug has other therapeutic indications, an evaluation of the drug's safety and efficacy may be performed in relation to those other therapeutic indications.

(f) In implementing this article, the Legislature requests that the University of California consider obtaining the assistance of other research universities and medical research centers in the state.

(g) It is the intent of the Legislature that the information posted on the program's Internet Web site be used to assist prescribers and patients in choosing the most appropriate therapy for each patient, and that the information not be used to exclude, restrict, or limit coverage and reimbursement for a medication recommended by a patient's prescriber.

(h) Any contract or agreement entered into between the department and the University of California pursuant to this section shall require that the University of California begin reporting on the safety and effectiveness of prescription drugs pursuant to this article on a date certain specified in the contract between the department and the University of California. It is the intent of the Legislature that this reporting begin as soon as it is feasible to do so.

(i) In order to avoid conflicts of interest, any contract or agreement entered into between the department and the University of California pursuant to this section shall require that the University of California develop and implement conflict-of-interest policies to prohibit a person from participating in the implementation or operation of the program's evaluation of a given class of prescription drugs when he or she knows or has reason to know that he or she has a material financial or other interest, including, but not limited to, a person who has a consulting or other agreement with an organization, that would be affected by the program's evaluation of that given class of prescription drugs. The contract shall require that these conflict-of-interest policies be consistent with, and as rigorous as, the policies utilized by the California Health Benefits Review Program pursuant to Section 127663.

SEC. 3. (j) The department shall, by December 1, 2011, and every year thereafter, until December 1, 2015, present to the Assembly Committee on Health and the Senate Committee on Health a report on the development of the prescription education service established pursuant to this section.

111657.1. (a) In order to effectively support the department and the University of California in implementing this article, there is hereby imposed, pursuant to this section, a fee on manufacturers of drugs sold in the state. The amount of the fee shall be determined by the department, in consultation with the University of California, and shall be limited to the amount necessary to fund the actual and

necessary expenses of the university, the department, and the State Board of Equalization in implementing this article. The total annual assessment on drug manufacturers shall not exceed three million five hundred thousand dollars ($3,500,000).

(b) (1) The specific fee to be assessed on a drug manufacturer shall be established by the department, to the maximum extent practicable, on the basis of a drug manufacturer's market share of the total amount of prescription drugs sold in the state, based on the total dispensed retail dollar amount in the year prior to the assessment.

(2) A fee shall not be assessed on a drug manufacturer that can demonstrate, as determined by the department, that it does not manufacture drugs that are advertised to consumers or marketed to physicians in the state.

(c) The fee shall be assessed and collected annually by the State Board of Equalization.

(1) For purposes of this section, the State Board of Equalization shall collect the drug manufacturer fee in accordance with the Fee Collection Procedures Law (Part 20 (commencing with Section 55001) of Division 2 of the Revenue and Taxation Code). The State Board of Equalization may prescribe, adopt, and enforce regulations to carry out this article, including, but not limited to, provisions governing collections, reporting, refunds, and appeals.

(2) The department shall provide to the State Board of Equalization the name and address of each person or entity who is liable for a fee or expense, the amount of the fee, and date the fee is due.

(3) No petition for redetermination of fees determined by the department pursuant to this section shall be considered by the State Board of Equalization if the petition is founded upon the grounds that the department has improperly or erroneously calculated the amount of the fee or has incorrectly determined that the person is subject to the fee. Any appeal of a determination based on the grounds that the amount of the fee was improperly or erroneously calculated or that the person is not responsible for the fee shall be accepted by the State Board of Equalization and forwarded to the department for consideration and decision.

(4) No claim for the refund of fees paid pursuant to this section shall be considered by the State Board of Equalization if the claim is founded upon the grounds that the department has improperly

or erroneously calculated the amount of the fee or has incorrectly determined that the person is subject to the fee. Any claim for refund based on the grounds that the amount of the fee was improperly or erroneously calculated or that the person is not responsible for the fee shall be accepted by the State Board of Equalization and forwarded to the department for consideration and decision.

(d) The fees collected shall be deposited into the Drug Safety and Effectiveness 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, but not limited to, paying refunds of the manufacturer drug fee imposed pursuant to this section, and to reimbursing administrative costs of the State Board of Equalization for collection of the fee. All interest earned on the moneys that have been deposited into the Drug Safety and Effectiveness Fund shall be retained in the fund.

(e) 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 establish fees pursuant to this section in excess of the amount reasonably anticipated by the University of California and the department, and the State Board of Equalization to fully implement this article.

(f) This section shall not be implemented until the department and the University of California enter into a contract or agreement pursuant to Section 111657. The department shall notify the State Board of Equalization when this contract or agreement has been entered into. The State Board of Equalization may delay collection of the first payment of the fee imposed by this section until seven and one-half months after the date that the department and the University of California enter into a contract or agreement pursuant to Section 111657.

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