AMENDED IN SENATE MAY 14, 2009

AMENDED IN SENATE MAY 6, 2009

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, *implemented only with federal or private funds or both,* 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, 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, and, until January 1, 2015, a prescription education service, as specified.

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. *Subject to subdivision (e), the University of California shall determine the classes of prescription drugs for purposes of this evaluation.*

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

(1) (A) An Internet Web site that will report information on the safety and effectiveness of brand name and generic drugs, 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.

(2) (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 (1).

(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, by January 1, 2011, 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, the program shall rely on the best scientific information that is available, as determined by the University of California, in consultation with the clinical advisory panel established pursuant to subdivision (d), giving due consideration to the diversity of the population of the State of California. When compiling evidence, the program 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) The program implemented pursuant to this section shall include 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~~ *implemented pursuant to this section* 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) The program implemented pursuant to this section shall 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, the program implemented pursuant to this section shall 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 conflict-of-interest policies shall be consistent with, and as rigorous as, the policies utilized by the California Health Benefits Review Program pursuant to Section 127663.

(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.

(k) This program shall be implemented only with federal or private or federal and private funds. In addition, this program shall be implemented only to the extent that the University of California determines that the program is not substantially similar to or has the same objectives as any other federally funded program.

O