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Prescription Drugs. Initiative Statute.

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Monday, January 24, 2005

Tricia Knight
Initiative Coordinator
Office of the Attorney General
P.O. Box 94425
Sacramento, CA 94244-2550

RECEIVED

JAN 24 2005

INITIATIVE COORDINATOR
ATTORNEY GENERAL'S OFFICE

Ms. Knight,

I hereby request the preparation of a title and summary for the enclosed proposed initiative measure.

Regards,

~~Gerard Flanagan~~
Proponent

Enclosed: Proponent's Voter Registration Address
Text of Proposed Initiative Measure
Payment for title and summary preparation

SECTION 1. Title.

This Act shall be known as the "Affordable and Safe Prescription Drugs for All Californians Act"

SECTION 2. Findings and Declarations.

The People of California find and declare the following:

Prescription drugs cost 70% more in California than they do in other countries. Drug companies knowingly sell dangerous drugs.

Other countries use their buying power to negotiate prescription drug discounts. The State of California negotiates drug discounts on behalf of state workers, elected officials and the Governor. Existing laws do not allow most Californians to access similar discounts.

Therefore, the People of California declare that reform is necessary. First, all Californians shall be allowed to join a discount program to access affordable prescription drugs at local pharmacies. This purchasing program will operate on a key market principle: the bigger the buyer, the better the price. Second, unfair price gouging by drug companies will be controlled. Third, drug companies and marketers will be required to tell doctors and the public about the health risks of prescription drugs. Drug companies and marketers shall pay a fee to cover the costs of administering these new laws so that this reform will cost taxpayers nothing.

SECTION 3. Purpose and Intent.

The purpose of this Act is to provide all Californians access to affordable and safe prescription drugs.

SECTION 4. Part 9 (commencing with Section 22980) is added to Division 5 of Title 2 of the Government Code, to read:

22980. This chapter shall be known and be cited as the Affordable and Safe Prescription Drugs for All Californians Act ("Act")

Article 1. Voluntary Access to Prescription Drug Discounts

22981. Any individual, regardless of income or insurance status, shall be allowed to join a prescription drug discount program administered by the Board of Administration of the Public Employees' Retirement System ("Board").

22982. The Board shall issue a pharmacy card to each new enrollee to access prescription drug discounts at the same pharmacies and pharmacy networks available to state workers. The Board shall provide enrollees access to a mail-order pharmacy option.

22983. The Board shall establish procedures for continuous open enrollment to the discount program. Enrollment forms shall be made available on the Board's Web site, at participating pharmacies, physician offices and at various other locations deemed appropriate by the Board.

22984. The Board may require an enrollee to pay an annual fee that proportionally reflects the administrative cost of providing prescription drug discounts to the enrollee, except that no enrollee fee shall be required if licensing fees and fines collected under Article 25 of Chapter 9 of Division 2 of the Business and Professions Code provide for the full cost of the program. The annual enrollee fee shall not exceed ten dollars (\$10) per year adjusted annually to reflect the rate of inflation.

22985. The Board may enter into contracts with entities offering services related to the administration of pharmacy benefits, or with an entity that negotiates price discounts, rebates or other savings on prescription drugs with prescription drug manufacturers, wholesalers, or pharmacies.

22986. (a) The Board shall inform the public about their eligibility under the Act through press releases, public services announcements, television, radio and newspaper advertisements, announcements on state websites and written materials, and other means. The Board shall coordinate outreach activities with the California Department of Aging and other state and local agencies.

(b) No outreach material shall contain the name or likeness of a prescription drug, pharmaceutical drug manufacturer, or elected official. The annual cost of these outreach activities shall not exceed \$1 million. If deemed appropriate by the Board, additional outreach and advertising expenses may be approved by the legislature by a statute passed in each house by roll call vote entered in the journal, fifty percent plus one of the membership concurring. Annual outreach costs shall be paid out of the Prescription Drug Discount Fund.

22987. The Prescription Drug Discount Fund is hereby established and shall be maintained in the State Treasury to accept fees related to enrollment in the program and licensing fees and fines collected under Article 25 of Chapter 9 of Division 2 of the Business and Professions Code. Notwithstanding Section 13340 of the Government Code, the fund is hereby continuously appropriated to the Board for purposes of the administration and maintenance of the pharmaceutical purchasing program.

22988. The Board may request from the state Legislature, and the Legislature shall provide, up to \$5,000,000 to pay for initial startup costs associated with the implementation of this Act. Licensing fees and fines collected under Article 25 of Chapter 9 of Division 2 of the Business and Professions Code shall be used to repay monies provided to pay for initial startup costs.

22989. Enrollees shall pay the discounted price for prescription drugs negotiated by the Board at participating pharmacies. The amount to be paid for those drugs by enrollees may include a pharmacy dispensing fee of no more than three dollars and fifty cents per prescription adjusted annually to reflect the rate of inflation.

22990. Following public comment, the Board may adopt a preferred drug list. If the Board adopts a preferred drug list, the Board shall provide for periodic public review of, and consider suggested changes to, the preferred drug list.

22991. The Board may adopt all necessary rules and regulations to carry out the provisions of this Act. The Board shall have the authority reasonably necessary to carry out the powers and responsibilities expressly granted or imposed upon it under this Act.

Article 2. End Drug Company Profiteering

22995. Profiteering in prescription drugs is unlawful and is subject to the provisions of this section. The provisions of this section apply to pharmaceutical drug manufacturers.

(a) A pharmaceutical drug manufacturer engages in illegal profiteering if that manufacturer:

- (1) Exacts or demands an excessive price;
- (2) Exacts or demands a price or terms that lead to any unjust or unreasonable profit;
- (3) Discriminates unreasonably against any person in the sale, exchange, distribution or handling of prescription drugs dispensed or delivered in the State; or
- (4) Intentionally prevents, limits, lessens or restricts the sale or distribution of prescription drugs in this State in retaliation for the provisions of this chapter.

(b) The Board shall adopt, no later than six (6) months after voter approval of this measure and following public hearings, regulations determining excessive price and unjust or unreasonable profit.

(c) Each violation of this section is a civil violation for which the Attorney General or any person acting for the interests of itself, its members or the general public may obtain, in addition to other remedies, disgorgement and restitution, injunctive relief and a civil penalty in an amount of \$100,000, plus the costs of suit, including necessary and reasonable investigative costs, reasonable expert fees and reasonable attorney's fees.

SECTION 5. Safe Prescription Drugs

Article 25 (commencing with Section 4450) is added to Chapter 9 of Division 2 of the Business and Professions Code, to read:

4450. (a) No person may act as a prescription drug marketer unless such person, and the pharmaceutical drug manufacturer represented by the person, has first secured a license from the Board of Pharmacy. The Board of Pharmacy shall implement this Article no later than six (6) months after voter approval of this measure.

(b) A person or manufacturer licensed under this Article:

- (1) Shall not engage in any unfair or deceptive acts or practices.

(2) Shall disclose to a physician or any other person licensed to prescribe prescription drugs in this state, the health risks of, and results of any clinical trials regarding the health risks of, each prescription drug directly marketed to the physician or other person authorized to prescribe prescription drugs.

(c) A manufacturer licensed under this section shall disclose on the manufacturer's website the health risks of, and the results of any clinical trials regarding the health risks of, each prescription drug marketed by a licensed marketer employed by or representing the manufacturer in this state.

4451. A person or pharmaceutical drug manufacturer who violates a provision of this Article may be subject to revocation or suspension of the license granted under this Article.

4452. (a) The Board of Pharmacy shall require each licensee that is not a pharmaceutical drug manufacturer to pay an annual fee of \$750.00.

(b) The Board of Pharmacy shall require a manufacturer employing or contracting for a prescription drug marketer or marketers in this state to pay an annual fee of \$25,000 per manufacturer.

4453. A person other than a pharmaceutical drug manufacturer who violates a provision of Article, including a person who engages in the activities of a prescription drug marketer after his or her license has been revoked or suspended, shall be fined \$5,000 by the Board of Pharmacy. A manufacturer who violates a provision of this Article shall be fined \$25,000 by the Board of Pharmacy. The Attorney General or a district attorney, county council, city attorney, or city prosecutor may bring a civil action to enforce the provisions of this Article. Each unlawful act of prescription drug promotional or marketing activity shall constitute a separate violation of this Article.

4454. License fees and fines shall be deposited into the Prescription Drug Discount Fund, as defined under Section 22987 of the Government Code, to pay for costs associated with the Affordable and Safe Prescription Drugs for All Californians Act. No more than \$2,000,000 of these fees and fines may be retained annually by the Board of Pharmacy to pay for necessary expenses related to the licensing and oversight of marketers and manufacturers. Additional funds to implement this section may be approved by the legislature by a statute passed in each house by a roll call vote entered in the journal, fifty percent plus one of the membership concurring.

4455. (a) The Board of Pharmacy may adopt all necessary rules and regulations to carry out the provisions of this Article. The Board of Pharmacy shall have the authority reasonably necessary to carry out the powers and responsibilities expressly granted or imposed upon it under this Article.

(b) In the event that the Board of Pharmacy ceases to exist, or its duties are subsumed by, or transferred to, another entity, the authorities and duties of this Article shall be transferred to the California Department of Health Services.

4456. For the purposes of this Article:

(a) “prescription drug marketer” or “marketer” means a person who, while employed by or under contract to represent a pharmaceutical manufacturing company, engages in pharmaceutical detailing, promotional activities, or other marketing of prescription drugs in this state to any physician or any other person licensed to prescribe prescription drugs.

(b) “Pharmaceutical drug manufacturer” or “manufacturer” means any entity which is engaged in the production, preparation, propagation, compounding, conversion, or processing of prescription drugs, either directly or indirectly by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis, or any entity engaged in the packaging, repackaging, labeling, relabeling, or distribution of prescription drugs. The term does not include a licensed pharmacist.

(c) “prescription drug” means any of the following:

(1) Any drug that bears the legend “Caution: federal law prohibits dispensing without prescription,” “Rx only,” or words of similar import.

(2) Any drug or device that, pursuant to federal or state law, may be dispensed only with a prescription, or that is furnished pursuant to Section 4006 of the Business and Professions Code.

(3) “prescription drug” does not include labeled veterinary drugs.

(d) “marketed” means any promotional or marketing activity carried out by the prescription drug marketer or pharmaceutical drug manufacturer.

(e) “Board of Pharmacy” means the California Board of Pharmacy.

(f) “clinical trial” means a systematic evidenced based research study designed to answer specific questions about new or existing prescription drugs, or new ways of using known treatments.

SECTION 6. Joint Purchasing

Section 22851 of the Government Code is amended to read:

The Board may enter into any joint purchasing arrangement with private or public entities if the arrangement does not jeopardize the system’s tax status or its governmental plan status.

SECTION 7. Definitions and Technical Matters

Section 22998 and 22999 are added to Part 9 of Division 5 of Title 2 of the Government Code, to read:

22998. For the purposes of this part:

(a) “Enrollee” means any individual enrolled in the prescription drug discount program provided by the Affordable and Safe Prescription Drugs for All Californians Act.

(b) "Program" or "discount program" means the prescription drug discount program provided by the Affordable and Safe Prescription Drugs for All Californians Act.

(c) "Board" means the Board of Administration of the Public Employees' Retirement System.

(d) "pharmaceutical drug manufacturer" or "manufacturer" means any entity which is engaged in the production, preparation, propagation, compounding, conversion, or processing of prescription drugs, either directly or indirectly by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis, or any entity engaged in the packaging, repackaging, labeling, relabeling or distribution of prescription drugs. The term does not include a licensed pharmacist.

(e) "prescription drug" means any of the following:

(1) Any drug that bears the legend "Caution: federal law prohibits dispensing without prescription," "Rx only," or words of similar import.

(2) Any drug or device that, pursuant to federal or state law, may be dispensed only with a prescription, or that is furnished pursuant to Section 4006 of the Business and Professions Code.

(3) "prescription drug" does not include labeled veterinary drugs.

22999. (a) This Act shall be broadly construed and applied in order to fully promote its underlying purposes. If any provision of this initiative conflicts directly or indirectly with any other provisions of law, or any other statute previously enacted by the Legislature, it is the intent of the voters that such provisions shall be null and void to the extent that they are inconsistent with this initiative and are hereby repealed.

(b) No provision of this Act may be amended by the legislature except to further the purposes of that provision by a statute passed in each house by roll call vote entered in the journal, two-third of the membership concurring, or by a statute that becomes effective only when approved by the electorate. No amendment by the legislature shall be deemed to further the purposes of this Act unless it furthers the purpose of the specific provision of this Act that is being amended. In any judicial action with respect to any legislative amendment, the court shall exercise its independent judgment as to whether or not the amendment satisfies the requirements of this subsection.

(c) If any provision of this Act or the application thereof to any person or circumstances is held invalid, that invalidity shall not affect other provisions or applications of the Act that can be given effect in the absence of the invalid provision or application. To this end, the provisions of this Act are severable.

(d) In the event that this measure and another measure or measures relating to prescription drug purchasing, discounts, or price negotiation shall appear on the same statewide election ballot, the provisions of the other measure or measures shall be deemed in conflict with this measure. In the event that this measure receives a greater number of affirmative votes, the provisions of this measure shall prevail in their entirety, and the other measure or measures shall be null and void.