

2001 DRAFTING REQUEST

Bill

Received: **09/27/2000**

Received By: **kenneda**

Wanted: **As time permits**

Identical to LRB:

For: **G. Spencer Coggs (608) 266-5580**

By/Representing: **Dave de Felice (aide)**

This file may be shown to any legislator: **NO**

Drafter: **kenneda**

May Contact:

Addl. Drafters:

Subject: **Health - miscellaneous**

Extra Copies: **ISR**

Submit via email: **NO**

Pre Topic:

No specific pre topic given

Topic:

Prescription drugs for elderly--Maine pricing plan

Instructions:

See Attached

Drafting History:

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Requester's email:

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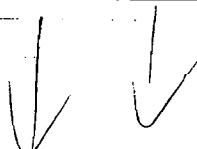
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THE SENATE OF MAINE
OFFICE OF THE MAJORITY LEADERS
3 STATE HOUSE STATION
AUGUSTA, MAINE 04333

Senator Chellie Pingree
Majority Leader

**Public Law #786
An Act to Establish Fairer Pricing
for Prescription Drugs**

**Chellie Pingree
Maine State Senate Majority Leader
(207) 287-1515**

AMENDMENT TO LD. 2599
An Act to Establish Fairer Prescription Drug Prices
SPONSORED BY SENATOR CHELLIE PINGREE

Our goal is to provide citizens immediate relief from the high cost of prescription drugs and time to negotiate the high cost of prescription drugs down to an affordable and accessible level.

Establishes the Maine Rx Program

- The State serves as a pharmaceutical benefit manager (PBM) for the estimated 325,000 Maine residents who have no prescription drug benefit as part of a private or public health insurance program. Those residents would be eligible to receive a Maine Rx card.
- Maine residents may be using the Maine Rx card and receive discounts on January 1, 2001 at participating retail pharmacies in Maine.
- Discounts increase as the State enters into rebate agreements with drug manufacturers. Holders of the Maine Rx card receive the benefit of manufacturer rebates, less minimal program administration costs.

Prevents Profiteering in Prescription Drugs and Manufacturer Retaliation Against the New Law

- but*
- A manufacturer or distributor of prescription drugs who charges an excessive price for prescription drugs or who restricts the supply of prescription drugs in the State may be assessed a civil penalty of up to \$100,000 for each such action. Courts may grant injunctions preventing such sales and award triple damages, costs of suit, and reasonable expert and attorney's fees.

Interstate Cooperation

- The state is authorized to enter into agreements with governments of other jurisdictions and with other public and private entities in order to ensure access to affordable prescription drugs for Maine residents.

Provides for Emergency Prescription Drug Prices

- but*
- By January 5, 2003, the State will determine whether prescription drug prices paid under the Maine Rx program are reasonably comparable to the lowest prescription drug prices paid in the State (taking into consideration the federal supply schedule and prices paid by large purchasers). If the prices are not reasonably comparable, the State will set maximum prices for prescription drugs by July 1, 2003.

Creates the Prescription Drug Advisory Commission

- The 12 member commission consists of members of the public including senior citizen advocates, prescribing members of the medical community, pharmacists, and administrative officials. The commission reviews access to prescription drugs for all Maine residents of the State, advises the Commissioner of Human Services on the implementation of the programs established by the new law, and reports annually to the Legislature and the Governor regarding affordable access to prescription drugs.

Pharmacy Participation

- A **
- Participation by pharmacies in the Maine Rx Program is optional.
 - An additional professional fee of \$3.00 is paid to pharmacies for each prescription filled.
 - The State guarantees timely payment of rebates and dispensing fees to pharmacies.

APPROVED

CHAPTER

MAY 11 00

786

BY GOVERNOR

PUBLIC LAW

STATE OF MAINE

IN THE YEAR OF OUR LORD
TWO THOUSAND

S.P. 1026 - L.D. 2599

An Act to Establish Fairer Pricing for Prescription Drugs

Be it enacted by the People of the State of Maine as follows:

PART A

Sec. A-1. 5 MRSA §12004-I, sub-§47-E is enacted to read:

<u>47-E.</u>	<u>Prescription</u>	<u>Expenses/</u>	<u>22 MRSA</u>
<u>Human</u>	<u>Drug</u>	<u>Legislative</u>	<u>\$2692.</u>
<u>Services</u>	<u>Advisory</u>	<u>Per Diem</u>	<u>sub-§6</u>
	<u>Commission</u>	<u>for</u>	
		<u>Nonsalaried</u>	
		<u>or Nonpaid</u>	
		<u>Public</u>	
		<u>Members</u>	

Sec. A-2. 22 MRSA §254-B, as enacted by PL 1999, c. 431, §1, is repealed.

Sec. A-3. 22 MRSA c. 603 is enacted to read:

CHAPTER 603

PRESCRIPTION DRUG ACCESS

SUBCHAPTER I

MAINE RX PROGRAM

§2681. Maine Rx Program established

The Maine Rx Program, referred to in this subchapter as the "program," is established to reduce prescription drug prices for residents of the State. The program is designed for the State to utilize manufacturer rebates and pharmacy discounts to reduce prescription drug prices. In implementing the program, the State shall serve as a pharmacy benefit manager in establishing rebates and discounts on behalf of qualified residents.

1. Program goals. The Legislature finds that affordability is critical in providing access to prescription drugs for Maine residents. This subchapter is enacted by the Legislature to enable the State to act as a pharmacy benefit manager in order to make prescription drugs more affordable for qualified Maine residents, thereby increasing the overall health of Maine residents, promoting healthy communities and protecting the public health and welfare. It is not the intention of the State to discourage employers from offering or paying for prescription drug benefits for their employees or to replace employer-sponsored prescription drug benefit plans that provide benefits comparable to those made available to qualified Maine residents under this subchapter.

2. Definitions. As used in this subchapter, unless the context otherwise indicates, the following terms have the following meanings.

A. "Average wholesale price" means the wholesale price charged on a specific commodity that is assigned by the drug manufacturer and is listed in a nationally recognized drug pricing file.

B. "Initial discounted price" means a price that is less than or equal to the average wholesale price, minus 6%, plus the dispensing fee provided under the Medicaid program under this Title.

C. "Labeler" means an entity or person that receives prescription drugs from a manufacturer or wholesaler and repackages those drugs for later retail sale and that has a labeler code from the federal Food and Drug Administration under 21 Code of Federal Regulations, 207.20 (1999).

D. "Participating retail pharmacy" or "retail pharmacy" means a retail pharmacy located in this State, or another business licensed to dispense prescription drugs in this State, that participates in the program and that provides discounted prices to residents as provided in subsection 5.

E. "Pharmacy benefit manager" means an entity that procures prescription drugs at a negotiated rate under a contract.

F. "Qualified resident" means a resident of the State who has obtained from the department a Maine Rx enrollment card.

G. "Secondary discounted price" means a price that is equal to or less than the initial discounted price minus the amount of any rebate paid by the State to the participating retail pharmacy.

3. Rebate agreement. A drug manufacturer or labeler that sells prescription drugs in this State through the elderly low-cost drug program under section 254 or any other publicly supported pharmaceutical assistance program shall enter into a rebate agreement with the department for this program. The rebate agreement must require the manufacturer or labeler to make rebate payments to the State each calendar quarter or according to a schedule established by the department.

4. Rebate amount. The commissioner shall negotiate the amount of the rebate required from a manufacturer or labeler in accordance with this subsection.

A. The commissioner shall take into consideration the rebate calculated under the Medicaid Rebate Program pursuant to 42 United States Code, Section 1396r-8, the average wholesale price of prescription drugs and any other information on prescription drug prices and price discounts.

B. The commissioner shall use the commissioner's best efforts to obtain an initial rebate amount equal to or greater than the rebate calculated under the Medicaid program pursuant to 42 United States Code, Section 1396r-8.

C. With respect to the rebate taking effect no later than October 1, 2001, the commissioner shall use the commissioner's best efforts to obtain an amount equal to or greater than the amount of any discount, rebate or price reduction for prescription drugs provided to the Federal Government.

5. Discounted prices for qualified residents. Any participating retail pharmacy that sells prescription drugs covered by a rebate agreement pursuant to subsection 3 shall discount the retail price of those drugs sold to qualified residents.

A. The department shall establish discounted prices for drugs covered by a rebate agreement and shall promote the

use of efficacious and reduced-cost drugs, taking into consideration reduced prices for state and federally capped drug programs, differential dispensing fees, administrative overhead and incentive payments.

B. Beginning January 1, 2001, a participating retail pharmacy shall offer the initial discounted price.

C. No later than October 1, 2001, a participating retail pharmacy shall offer the secondary discounted price.

D. In determining the amount of discounted prices, the department shall consider an average of all rebates provided pursuant to subsection 4, weighted by sales of drugs subject to these rebates over the most recent 12-month period for which the information is available.

6. Operation of program. The requirements of this subsection apply to participating retail pharmacies.

A. The Maine Board of Pharmacy shall adopt rules requiring disclosure by participating retail pharmacies to qualified residents of the amount of savings provided as a result of the program. The rules must consider and protect information that is proprietary in nature. Rules adopted pursuant to this paragraph are routine technical rules as defined in Title 5, chapter 375, subchapter II-A.

B. The department may not impose transaction charges under this program on retail pharmacies that submit claims or receive payments under the program.

C. A participating retail pharmacy shall submit claims to the department to verify the amount charged to qualified residents under subsection 5.

D. On a weekly or biweekly basis, the department must reimburse a participating retail pharmacy for discounted prices provided to qualified residents under subsection 5 and professional fees, which must be set by the commissioner. The amount of the initial professional fee must be set at \$3 per prescription.

E. The department shall collect utilization data from the participating retail pharmacies submitting claims necessary to calculate the amount of the rebate from the manufacturer or labeler. The department shall protect the confidentiality of all information subject to confidentiality protection under state or federal law, rule or regulation.

7. Action with regard to nonparticipating manufacturers and labelers. The names of manufacturers and labelers who do not enter into rebate agreements pursuant to this subchapter are public information. The department shall release this information to health care providers and the public. The department shall impose prior authorization requirements in the Medicaid program under this Title, as permitted by law, for the dispensing of prescription drugs provided by those manufacturers and labelers.

8. Discrepancies in rebate amounts. Discrepancies in rebate amounts must be resolved using the process established in this subsection.

A. If there is a discrepancy in the manufacturer's or labeler's favor between the amount claimed by a pharmacy and the amount rebated by the manufacturer or labeler, the department, at the department's expense, may hire a mutually agreed-upon independent auditor. If a discrepancy still exists following the audit, the manufacturer or labeler shall justify the reason for the discrepancy or make payment to the department for any additional amount due.

B. If there is a discrepancy against the interest of the manufacturer or labeler in the information provided by the department to the manufacturer or labeler regarding the manufacturer's or labeler's rebate, the manufacturer or labeler, at the manufacturer's or labeler's expense, may hire a mutually agreed-upon independent auditor to verify the accuracy of the data supplied to the department. If a discrepancy still exists following the audit, the department shall justify the reason for the discrepancy or refund to the manufacturer any excess payment made by the manufacturer or labeler.

C. Following the procedures established in paragraph A or B, either the department or the manufacturer or labeler may request a hearing before the Administrative Hearings Unit. Supporting documentation must accompany the request for a hearing.

9. Dedicated fund. The Maine Rx Dedicated Fund, referred to in this section as the "fund," is established to receive revenue from manufacturers and labelers who pay rebates as provided in subsection 4 and any appropriations or allocations designated for the fund. The purposes of the fund are to: reimburse retail pharmacies for discounted prices provided to qualified residents pursuant to subsection 5; to reimburse the department for contracted services, administrative and associated

computer costs, professional fees paid to participating retail pharmacies and other reasonable program costs; and to benefit the elderly low-cost drug program under section 254. The fund also must be used in fiscal year 2002-03 to repay the working capital advance made to the program during fiscal year 2000-01 from the Trust Fund for a Healthy Maine, established in section 1512. The fund is a nonlapsing dedicated fund. Interest on fund balances accrues to the fund. Surplus funds in the fund must be used for the benefit of the program. Notwithstanding Title 5, section 1585, surplus funds may also be transferred to the elderly low-cost drug program established under section 254.

10. Annual summary report. The department shall report the enrollment and financial status of the program to the Legislature by the 2nd week in January each year.

11. Obligations of department. The department shall establish simplified procedures for determining eligibility and issuing Maine Rx enrollment cards to qualified residents and shall undertake outreach efforts to build public awareness of the program and maximize enrollment of qualified residents. The department may adjust the requirements and terms of the program to accommodate any new federally funded prescription drug programs.

12. Contracting. The department may contract with a 3rd-party or 3rd-parties to administer any or all components of the program, including, but not limited to, outreach, eligibility, claims, administration and rebate recovery and redistribution.

13. Medical assistance programs. The department shall administer the program and other medical and pharmaceutical assistance programs under this Title in a manner that is advantageous to the programs and to the enrollees in those programs. In implementing this subsection the department may coordinate the other programs and this program and may take actions to enhance efficiency, reduce the cost of prescription drugs and maximize the benefits to the programs and enrollees, including providing the benefits of this program to enrollees in other programs.

14. Rulemaking. The department may adopt rules to implement the provisions of this section. Rules adopted pursuant to this subsection are routine technical rules as defined in Title 5, chapter 375, subchapter II-A.

15. Waivers. The department may seek any waivers of federal law, rule or regulation necessary to implement the provisions of this subchapter.

SUBCHAPTER II

PRESCRIPTION DRUG PRICE REDUCTION ACT

§2691. Short title; purpose

This subchapter may be known and cited as the "Prescription Drug Price Reduction Act." The Legislature finds that affordability is critical in providing access to prescription drugs for Maine residents. This subchapter is enacted by the Legislature as a positive measure to make prescription drugs more affordable for qualified Maine residents, thereby increasing the overall health of Maine residents, promoting healthy communities and protecting the public health and welfare of Maine residents.

§2692. Prescription Drug Advisory Commission

The Prescription Drug Advisory Commission, referred to in this subchapter as the "commission," is established to review access to and the pricing of prescription drugs for residents of the State, to advise the commissioner on prescription drug pricing and to provide periodic reports to the commissioner, the Governor and the Legislature.

1. Membership. The commission consists of the following 12 members:

A. Three members of the public, appointed by the President of the Senate, one of whom must represent the interests of senior citizens. Of the initial appointees, one must be appointed for a 2-year term and 2 for 3-year terms;

B. Three members of the public, appointed by the Speaker of the House, one of whom must represent the interests of senior citizens. Of the initial appointees, one must be appointed for a 2-year term and 2 for 3-year terms;

C. Two members of the health care community who are authorized by the laws of this State to prescribe drugs, appointed by the Governor. Of the initial appointees, one must be appointed for a 2-year term and one for a 3-year term;

D. Two pharmacists, appointed by the Governor. Of the initial appointees, one must be appointed for a 2-year term and one for a 3-year term. To be appointed to and remain on the commission, each pharmacist must:

(1) Be licensed to practice pharmacy and be engaged in the practice of retail pharmacy in this State;

(2) Have at least 5 years of experience in this State as a licensed pharmacist; and

(3) Be a resident of this State; and

E. The Director of the Bureau of Medical Services and the Commissioner of Professional and Financial Regulation, or their designees, who shall serve as ex officio, nonvoting members.

2. Terms. With the exception of the initial appointees, all members of the commission serve for terms of 3 years and may be reappointed. With the exception of the pharmacist members, if the profession or qualifications of a commission member change during the term of commission membership, the member may continue to complete the term for which the appointment was made.

3. Meetings; chair. The commission shall meet at least 4 times per year. The members shall select a chair from among the members. Additional meetings may be called by the chair.

4. Duties. The duties of the commission include the following:

A. To review access to prescription drugs for residents of the State, including, but not limited to, pricing and affordability information;

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B. To advise the commissioner on access to prescription drugs and prescription drug prices, including, but not limited to, insurance and 3rd-party payments for prescription drugs, the need for maximum retail prices, and, if maximum retail prices are established, the procedures for adoption and periodic review of maximum retail prices, the procedures for establishing maximum retail prices for new prescription drugs and for reviewing maximum retail prices of selected drugs and the procedures for phasing out or terminating maximum retail prices;

C. To advise the commissioner on the adoption of rules necessary to implement this subchapter; and

D. To report to the commissioner, the Legislature and the Governor by April 1, 2001, and annually thereafter by the 2nd week in January, including in the report any recommendations for action regarding access to and the pricing of prescription drugs.

5. Staffing. The department shall provide staffing for the commission.

6. Compensation. Public members not otherwise compensated by their employers or other entities whom they represent are entitled to receive reimbursement of necessary expenses and a per diem equal to the legislative per diem for their attendance at authorized meetings of the commission.

7. Cooperation. In performing its duties, the commission shall work with the department, the Maine Board of Pharmacy and the Department of Professional and Financial Regulation.

§2693. Emergency drug pricing

In order to achieve the public health purposes listed in section 2691, maximum retail prices for prescription drugs sold in Maine may be established pursuant to this section.

1. Emergency drug pricing procedures. The following provisions apply to determinations regarding maximum retail prices for prescription drugs and to the procedures for establishing those prices.

A. By July 1, 2002, the department shall adopt rules establishing the procedures for adoption and periodic review of maximum retail prices, the procedures for establishing maximum retail prices for new prescription drugs and for reviewing maximum retail prices of selected drugs and the procedures for phasing out or terminating maximum retail prices. Prior to adopting rules pursuant to this paragraph, the commissioner shall consult with and consider the recommendations of the commission regarding the rules.

B. By January 5, 2003, the commissioner shall determine whether the cost of prescription drugs provided to qualified residents under the Maine Rx Program pursuant to subchapter I is reasonably comparable to the lowest cost paid for the same drugs delivered or dispensed in the State. In making this determination the following provisions apply.

(1) The commissioner shall review prescription drug use in the Medicaid program using data from the most recent 6-month period for which data is available.

(2) Using the data reviewed in subparagraph (1), the commissioner shall determine the 100 drugs for which the most units were provided and the 100 drugs for which the total cost was the highest.

(3) For each prescription drug listed in subparagraph (2), the commissioner shall determine the cost for each drug for qualified residents provided those drugs under the Maine Rx Program on a certain date. The average cost for each such drug must be calculated.

(4) For each prescription drug listed in subparagraph (2), the commissioner shall determine the lowest cost for each drug paid by any purchaser on the date that is used for subparagraph (3) delivered or dispensed in the State, taking into consideration the federal supply schedule and prices paid by pharmaceutical benefits managers and by large purchasers and excluding drugs purchased through the Maine Rx Program. The average cost for each such drug must be calculated.

(5) If the average cost for one or more prescription drugs under the Maine Rx Program as determined in subparagraph (3) is not reasonably comparable to the average lowest cost for the same drug or drugs as determined in subparagraph (4), the commissioner shall establish maximum retail prices for any or all prescription drugs sold in the State. Maximum prescription drug prices established under this subparagraph must take effect July 1, 2003.

C. In establishing maximum retail prices under this paragraph, the commissioner shall consider the advice of the commission and shall follow procedures set forth by rules adopted by the department.

D. Rules adopted pursuant to this subsection are major substantive rules as defined in Title 5, chapter 375, subchapter II-A.

2. Select prescription drugs. In making a determination under this section the commissioner may rely on pricing information on a selected number of prescription drugs if that list is representative of the prescription drug needs of the residents of the State and is made public as part of the process of establishing maximum retail prices.

3. Public health or welfare. The commissioner may take actions that the commissioner determines necessary if there is a severe limitation or shortage of or lack of access to prescription drugs in the State that could threaten or endanger the public health or welfare.

4. Appeals. A retailer of prescription drugs may appeal the maximum retail price of a prescription drug established pursuant to this section in accordance with the Maine Administrative Procedure Act.

5. Enforcement. A violation of the maximum retail prices established under this section is a violation of the Maine Unfair Trade Practices Act.

§2694. Rulemaking

With the exception of rules designated in this subchapter as major substantive rules, rules adopted pursuant to this subchapter are routine technical rules as defined by Title 5, chapter 375, subchapter II-A.

SUBCHAPTER III

PROFITEERING IN PRESCRIPTION DRUGS

§2697. Profiteering in prescription drugs

Prescription drugs are a necessity of life. Profiteering in prescription drugs is unlawful and is subject to the provisions of this section. The provisions of this section apply to manufacturers, distributors and labelers of prescription drugs.

1. Definitions. As used in this subchapter, unless the context otherwise indicates, the following terms have the following meanings.

A. "Labeler" means an entity or person that receives prescription drugs from a manufacturer or wholesaler and repackages those drugs for later retail sale and that has a labeler code from the federal Food and Drug Administration under 21 Code of Federal Regulations, 207.20 (1999).

B. "Manufacturer" means a manufacturer of prescription drugs and includes a subsidiary or affiliate of a manufacturer.

2. Profiteering. A manufacturer, distributor or labeler of prescription drugs engages in illegal profiteering if that manufacturer, distributor or labeler:

A. Exacts or demands an unconscionable price;

B. Exacts or demands prices or terms that lead to any unjust or unreasonable profit;

C. Discriminates unreasonably against any person in the sale, exchange, distribution or handling of prescription drugs dispensed or delivered in the State; or

D. Intentionally prevents, limits, lessens or restricts the sale or distribution of prescription drugs in this State in retaliation for the provisions of this chapter.

3. Right of action and damages. The State may bring a civil action in District Court or Superior Court for a direct or indirect injury to any person, group of persons, the State or a political subdivision of the State caused by a violation of this subchapter. There is a right to a jury trial in any action brought in Superior Court under this section. If the State prevails, the defendant shall pay 3 times the amount of damages and the costs of suit, including necessary and reasonable investigative costs, reasonable expert fees and reasonable attorney's fees. For a willful or repeated violation of this section, punitive damages may be awarded. After deduction of the costs of distribution, the damages must be equitably distributed by the State to all injured parties.

4. Civil violation. Each violation of this section is a civil violation for which the Attorney General may obtain, in addition to other remedies, injunctive relief and a civil penalty in an amount not to exceed \$100,000, plus the costs of suit, including necessary and reasonable investigative costs, reasonable expert fees and reasonable attorney's fees.

5. Unfair trade practice. A violation of this section is also a violation of the Maine Unfair Trade Practices Act.

§2698. Investigation by Attorney General

The Attorney General, upon the Attorney General's own initiative or upon petition of the commissioner or of 50 or more residents of the State, shall investigate suspected violations of this subchapter.

The Attorney General may require, by summons, the attendance and testimony of witnesses and the production of books and papers before the Attorney General related to any such matter under investigation. The summons must be served in the same manner as summonses for witnesses in criminal cases, and all provisions of law related to criminal cases apply to summonses issued under this section so far as they are applicable. All investigations or hearings under this section to which witnesses are summoned or called upon to testify or to produce books, records or correspondence are public or private at the choice of the person

summoned and must be held in the county where the act to be investigated is alleged to have been committed, or if the investigation is on petition, it must be held in the county in which the petitioners reside. The expense of the investigation must be paid from the appropriation provided in Title 5, section 203.

A Justice of the Superior Court may by order, upon application of the Attorney General, compel the attendance of witnesses, the production of books and papers, including correspondence, and the giving of testimony before the Attorney General in the same manner and to the same extent as before the Superior Court. Any failure to obey such an order may be punishable by that court as a contempt.

Sec. A-4. Agreements with governments of other jurisdictions and other entities. The State may negotiate and enter into purchasing alliances and regional strategies with the governments of other jurisdictions and with other public and private entities for the purpose of reducing prescription drug prices for residents of the State.

Sec. A-5. Findings; intent; purpose.

1. Findings. The Legislature makes the following findings.

A. Pharmaceutical companies are charging the citizens of Maine excessive prices for prescription drugs, denying Maine citizens access to medically necessary health care and thereby threatening their health and safety. Many Maine citizens are admitted to or treated at hospitals each year because they can not afford the drugs prescribed for them that could have prevented the need for hospitalization. Many others must enter expensive institutional care settings because they can not afford their necessary prescription drugs that could have supported them outside of an institution. All Maine citizens are threatened by the possibility that when they need medically necessary prescription drugs most they may be unable to afford their doctor's recommended treatment.

B. Citizens of Maine and other Americans pay the highest prices in the world for prescription drugs, prices that result in extremely high profits for pharmaceutical companies.

C. Prescription drug costs represent the fastest growing item in health care and are a driving force in rapidly increasing hospital costs and insurance rates.

D. Excessive pricing for prescription drugs threatens Maine's ability to assist with the health care costs of Maine citizens, undermines the financial capacity of Maine communities to meet the educational needs of Maine children, hurts the ability of the Maine business community to provide health insurance coverage to Maine's work force and has a negative effect on Maine's economy. The Legislature finds that affordability is critical in providing access to prescription drugs for Maine residents.

2. **Intent.** It is the intent of the Legislature to provide access for all Maine citizens to medically necessary prescription drugs at the lowest possible prices.

3. **Purpose.** This law is enacted by the Legislature as a positive measure to make prescription drugs more affordable for Maine residents, thereby increasing the overall health of our families, benefiting employers and employees and the fiscal strength of our society, promoting healthy communities and increasing the public health and welfare.

Sec. A-6. Appointments; first meeting of Prescription Drug Advisory Commission. All appointments must be completed no later than 30 days following the effective date of this Act. The appointing authorities shall notify the Executive Director of the Legislative Council upon making their appointments. The Chair of the Legislative Council shall call the first meeting of the commission within 30 days after notification that appointments have been completed. At the first meeting of the commission, the members shall select a chair from among the members.

Sec. A-7. Working capital advance. Notwithstanding the Maine Revised Statutes, Title 22, section 1511, subsection 3 and section 1512, the State Controller is authorized to advance to the Maine Rx Dedicated Fund in the Department of Human Services \$4,582,500 from the Trust Fund for a Healthy Maine no later than January 1, 2001. These funds may be allotted by financial order upon the recommendation of the State Budget Officer and approval of the Governor. These funds must be returned to the Trust Fund for a Healthy Maine from the Maine Rx Dedicated Fund no later than June 30, 2005.

Sec. A-8. Appropriation. The following funds are appropriated from the General Fund to carry out the purposes of this Part.

2000-01

HUMAN SERVICES, DEPARTMENT OF

Maine Rx Program

Positions - Legislative Count	(6,000)
Personal Services	\$148,330
All Other	502,750

Provides for the one-time appropriation of funds to establish the Maine Rx Program, including the establishment of 6 additional positions and related operating costs, for outreach activities, to contract for claims management services and for costs associated with the issuance of prescription cards.

**DEPARTMENT OF HUMAN SERVICES
TOTAL**

\$651,080

ATTORNEY GENERAL, DEPARTMENT OF THE

Administration - Attorney General

Positions - Legislative Count	(1,000)
Personal Services	\$46,745
All Other	5,340

TOTAL

52,085

Provides one-time funds for one Assistant Attorney General position and related operating costs due to the establishment of the Maine Rx Program.

Fair Drug Pricing Contingent Account

All Other	\$130,000
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Provides one-time funds to support litigation costs associated with the Maine Rx Program. Any balance remaining at the end of each fiscal year may not lapse but

must be carried forward to be used for the same purpose.

**DEPARTMENT OF THE ATTORNEY GENERAL
TOTAL**

\$182,085

TOTAL APPROPRIATIONS

\$833,165

Sec. A-9. Allocation. The following funds are allocated from the Other Special Revenue funds to carry out the purposes of this Part.

2000-01

**PROFESSIONAL AND FINANCIAL
REGULATION, DEPARTMENT OF**

Licensing and Enforcement

All Other

\$2,500

Provides for the allocation of funds for the costs associated with the Maine Board of Pharmacy to adopt rules associated with the Maine Rx Program.

PART B

Sec. B-1. 22 MRSA §254, sub-§8, as corrected by RR 1999, c. 1, §27, is amended to read:

8. Drug rebate program. Effective May 1, 1992, payment must be denied for drugs from manufacturers that do not enter into a rebate agreement with the department for prescription drugs included in the list of approved drugs under this program. Each agreement must provide that the pharmaceutical manufacturer make rebate payments for both the basic and supplemental components of the program to the department according to the following schedule.

~~A. For the period beginning May 1, 1992 and ending September 30, 1992, the rebate percentage is equal to 11% of the manufacturer's wholesale price for the total number of dosage units of each form and strength of a prescription drug that the department reports as reimbursed to providers of prescription drugs, provided payments are not due until 30 days following the manufacturer's receipt of utilization~~

~~data-supplied-by-the-department,-including-the-number-of dosage-units-reimbursed-to-providers-of-prescription-drugs during-the-period-for-which-payment-is-due.~~

B. For the quarters beginning October 1, 1992, the rebate percentage is equal to the percentage recommended by the federal Health Care Financing Administration of the manufacturer's wholesale price for the total number of dosage units of each form and strength of a prescription drug that the department reports as reimbursed to providers of prescription drugs, provided payments are not due until 30 days following the manufacturer's receipt of utilization data supplied by the department, including the number of dosage units reimbursed to providers of prescription drugs during the period for which payments are due.

C. Beginning October 1, 1998, the department shall seek to achieve an aggregate rebate amount from all rebate agreements that is 6 percentage points higher than that required by paragraph B of this subsection, provided such rebates result in a net increase in the rebate revenue available to the elderly low-cost drug program. In the event the department is not able to achieve the rebate amount required by this paragraph without compromising the best interest of recipients of the elderly low-cost drug program, it shall report to the joint standing committee of the Legislature having jurisdiction over health and human services matters and the joint standing committee of the Legislature having jurisdiction over appropriations and financial affairs in the First Regular Session of the 119th Legislature.

Upon receipt of data from the department, the pharmaceutical manufacturer shall calculate the quarterly payment. If a discrepancy is discovered, the department may, at its expense, hire a mutually agreed-upon independent auditor to verify the pharmaceutical manufacturer's calculation. If a discrepancy is still found, the pharmaceutical manufacturer shall justify its calculation or make payment to the department for any additional amount due. The pharmaceutical manufacturer may, at its expense, hire a mutually agreed-upon independent auditor to verify the accuracy of the utilization data provided by the department. If a discrepancy is discovered, the department shall justify its data or refund any excess payment to the pharmaceutical manufacturer.

If the dispute over the rebate amount is not resolved, a request for a hearing with supporting documentation must be submitted to the Administrative Hearings Unit. Failure to resolve the dispute

may be cause for terminating the drug rebate agreement and denying payment to the pharmaceutical manufacturer for any drugs.

~~All prescription drugs of a pharmaceutical manufacturer who enters into an agreement pursuant to this subsection that appear on the approved list of drugs must be immediately available and the cost of the drugs must be reimbursed and is not subject to any restrictions or prior authorization requirements. Any prescription drug of a manufacturer that does not enter into an agreement is not reimbursable unless the department determines the prescription drug is essential.~~

All prescription drugs of a pharmaceutical manufacturer that enters into an agreement pursuant to this subsection that appear on the list of approved drugs under this program must be immediately available and the cost of the drugs must be reimbursed and is not subject to any restrictions or prior authorization requirements, except as provided in this paragraph. If the commissioner establishes maximum retail prices for prescription drugs pursuant to section 2693, the department shall adopt rules for the elderly low-cost drug program requiring the use of a drug formulary and prior authorization for the dispensing of certain drugs to be listed on a formulary. Rules adopted pursuant to this paragraph are routine technical rules as defined in Title 5, chapter 375, subchapter II-A.

Sec. B-2. 22 MRSA §254, sub-§8-A is enacted to read:

8-A. Participation requirement. Beginning January 1, 2001, all manufacturers and labelers of drugs that participate in the Medicaid program under this Title must participate in the drug rebate program under subsection 8. For the purposes of this subsection, "labeler" means an entity or person that receives prescription drugs from a manufacturer or wholesaler and repackages those drugs for later retail sale and that has a labeler code from the federal Food and Drug Administration under 21 Code of Federal Regulations, 207.20 (1999).

Sec. B-3. 22 MRSA §3174-Y is enacted to read:

§3174-Y. Prior authorization in Medicaid program

If the commissioner establishes maximum retail prices for prescription drugs pursuant to section 2693, the department shall adopt rules for the Medicaid program requiring additional prior authorization for the dispensing of drugs determined to be priced above the established maximum retail prices. The department shall adopt rules for the Medicaid program requiring additional prior authorization for the dispensing of drugs provided from manufacturers and labelers who do not enter into agreements with

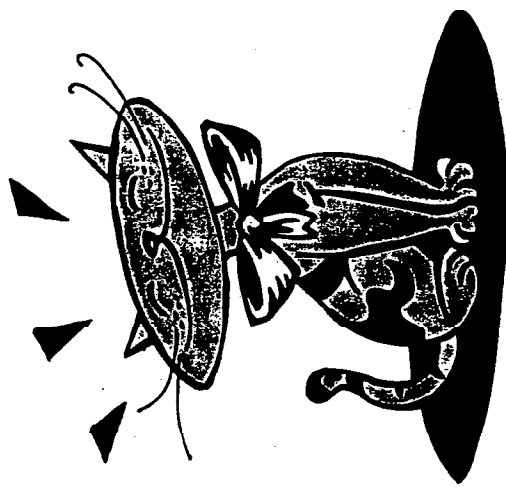
the department under section 2681, subsection 3. For the purposes of this section, "labeler" means an entity or person that receives prescription drugs from a manufacturer or wholesaler and repackages those drugs for later retail sale and that has a labeler code from the federal Food and Drug Administration under 21 Code of Federal Regulations, 207.20 (1999).

Table 1: Maine Seniors Pay Significantly Higher Retail Prices for Prescription Drugs Than Consumers in Canada or Mexico.

Prescription Drug	U.S. Dosage and Form	Canadian Retail Price	Mexican Retail Price	Maine Retail Price	Canada-Maine Price Differential	Mexico-Maine Price Differential
Zocor	5 mg 60 tablets	\$43.97	\$47.29	\$103.92	136%	120%
Ticlid	250 mg 60 tablets	\$52.35	\$39.61	\$117.96	125%	198%
Prilosec	20 mg 30 cap.	\$53.51	\$29.46	\$111.89	109%	280%
Relafen	500 mg 100 tablets	\$59.55	\$49.26	\$116.39	95%	136%
Zoloff	50 mg 100 tablets	\$124.41	\$155.52	\$213.28	71%	37%
Procardia XL	30 mg 100 tablets	\$72.82	\$87.78	\$118.85	63%	35%
Fosamax	10 mg 30 tablets	\$45.01	\$51.33	\$61.66	37%	20%
Vasotec	10 mg 100 tablets	\$73.42	\$57.03	\$96.49	31%	69%
Norvasc	5 mg 90 tablets	\$87.71	\$88.08	\$111.71	27%	27%
Cardizem CD	240 mg 90 tablets	\$142.70	\$88.14	\$174.99	23%	99%
Average Differential					72%	102%

Minority Staff Report Committee on Government Reform and Oversight
 US House of Representative, October 24, 1998

Retail-Level Prices are More Expensive for Human Consumers in Maine than for Animal Owners



Avg. Retail Price at
Veterinary Pharmacy



Avg. Retail Price
for Humans

Lanoxin	\$5.41	\$39.31
Bactroban	\$14.50	\$48.30

Prices based on monthly supply
Committee on Government Reform U.S. House of Representatives, Nov. 8, 1999

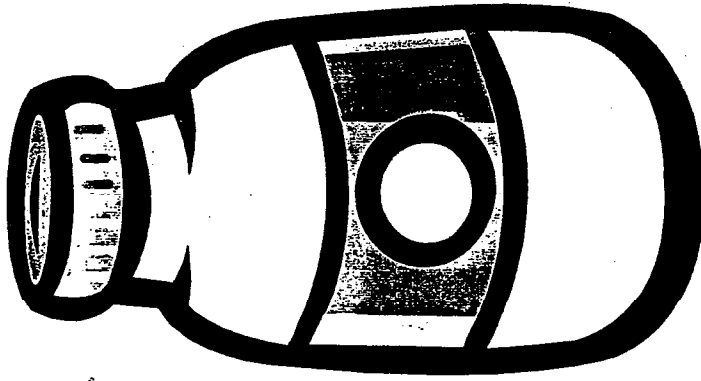
1996 Pharmaceutical R & D Spending in US, Western Europe and Japan

Country or Region	Pharmaceutical R & D (US \$)	Percent of Total for Three Regions
United States	\$13.6 billion	39.9%
Western Europe	\$14.4 billion	42.2%
Japan	\$6.1 billion	17.9%
Total for Three Regions	\$34.1 billion	100%

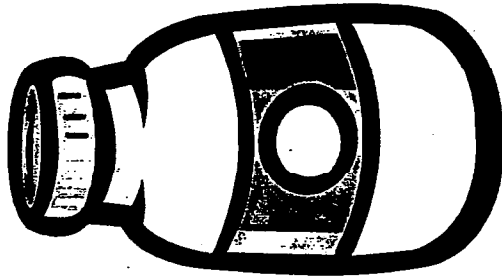
Countries of Western Europe, where prescription drug prices are 25% to 50% less than in the US, due to governmental negotiations, are also home to significant pharmaceutical research. The pharmaceutical industry defends high cost by saying that profits have made the US the world leader in development of new drugs.

Inflated R & D Expenditures

Donald Drake and Maran Uhlman,
Making Medicine, Making Money
(1993), p. 72



50%



30%

Only 30% R & D expenditure is spent on discovery of new medicines; more than 50% of drug approvals are for "me-too" drugs offering little or no therapeutic gain.

New Chemical Entities (NCE) Developed by Major Country or Group, 1990-1994

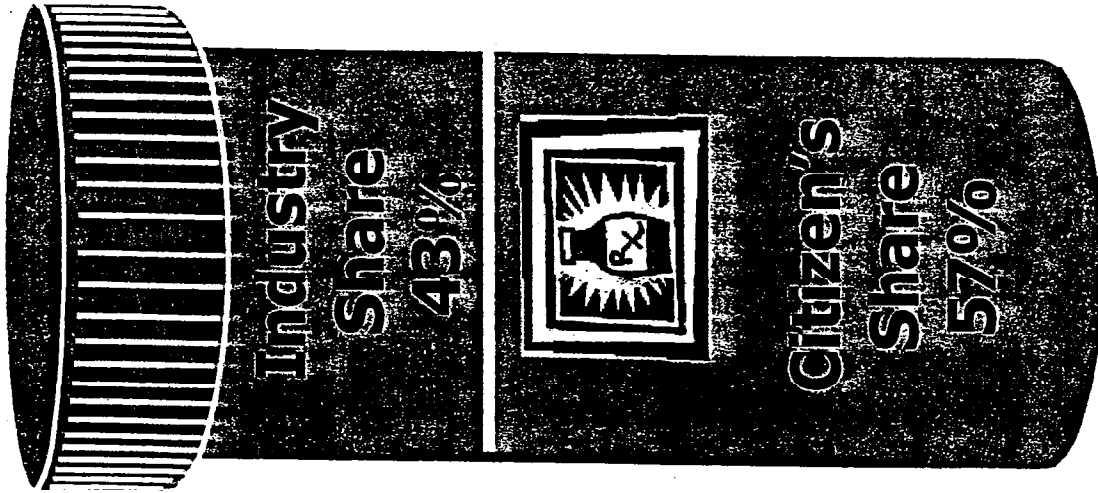
Country or Region	Total NCEs Developed	Percent of Total
United States	84	32.4%
Western Europe	94	36.3%
Japan	77	29.7%
All Other Countries	4	1.6%
World Total	259	100.0%

USITC Study, page 2-3

The U.S does not outshine the world in breakthrough research, as measured in the above table, by the number of new chemical entities developed.

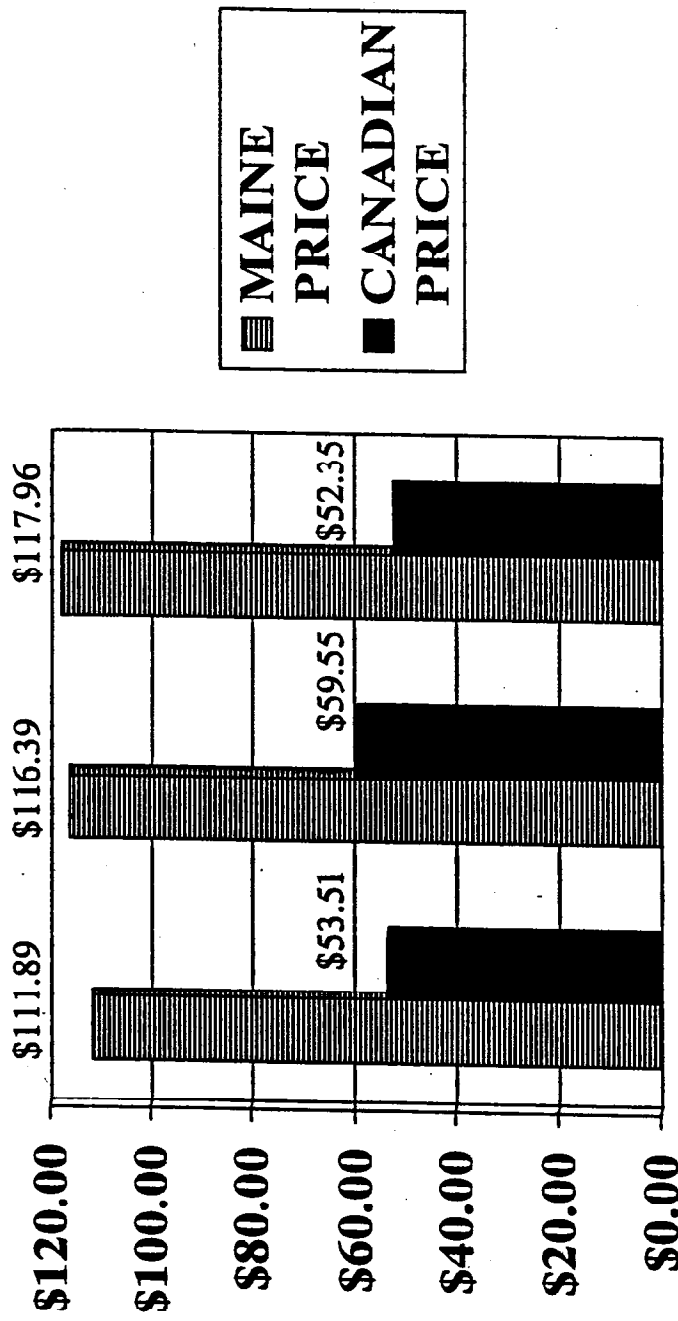
U.S. Taxes Pay for R & D

Pharmaceutical Research & Manufacturers of America testimony,
Vermont Senate, 1999.



**Citizens pay for more than half
the cost of Research and
Development for new drugs.**

**Maine vs.
Canadian
Prescription
Drug Prices**

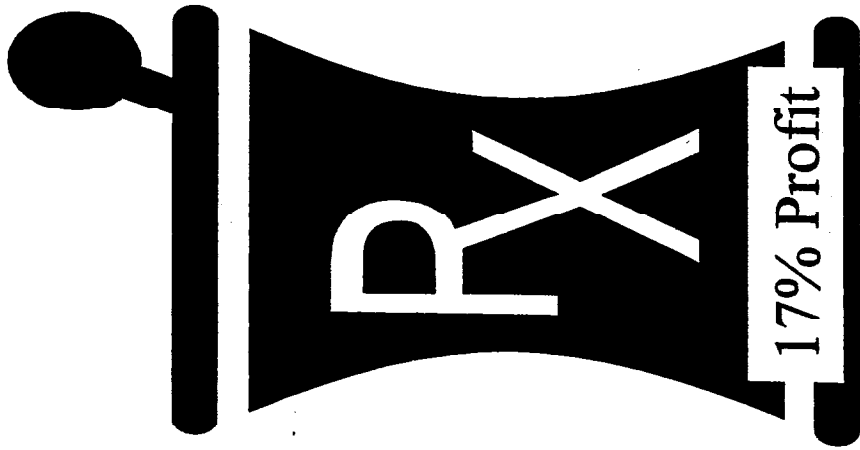


Prilosec Relafen Ticlid

Minority Staff Report Committee on Government Reform and Oversight, US House of Representatives, October, 1998

Profits Compared to Other Industries

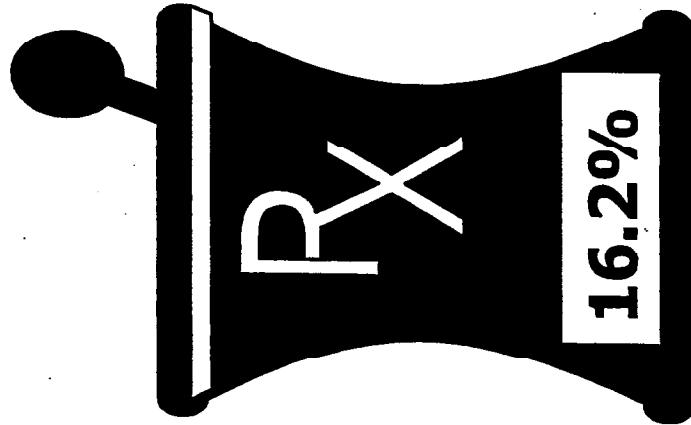
Congressional research service



**Drug Company Profits Are More
Than 3 Times Higher Than the
Average Profits of All Other
Industries**

Drug Companies Pay Lower Taxes

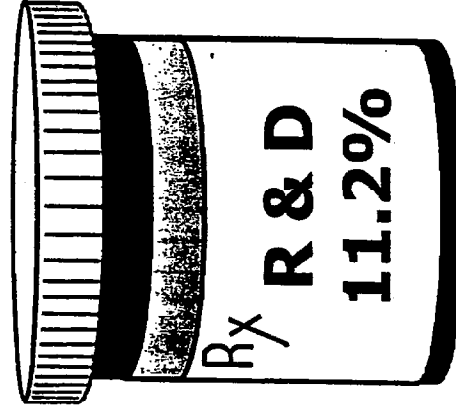
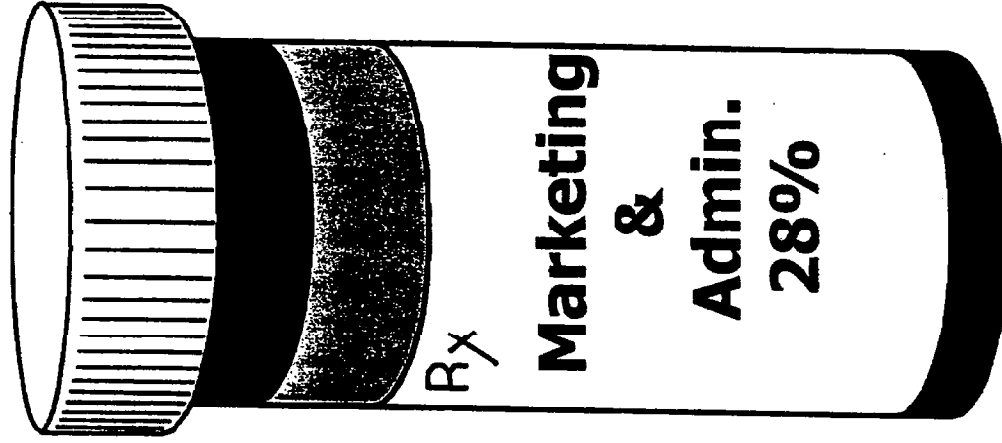
Congressional research service



The drug industry pays an average 41% fewer taxes than other industries

Marketing VS R & D

Pfizer and Merck companies, 1997 annual reports



Drug companies spend more on Marketing and Administration than On Research and Development.



FOR IMMEDIATE RELEASE
 April 14, 2000

Contact : Market Decisions
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 Curtis Mildner ext 105
 Dr. Brian Robertson ext 140
 Maine Times
 Doug Rooks 991-6640

Mainers Express Concern over Prescription Drug Prices and Support State Government Efforts to Control Pricing

A new Market Decisions survey for Maine Times indicates the average Maine household spent \$118 during the past three months on prescription drugs and a majority favor government efforts to control prescription drug prices.

The study was conducted among 401 randomly chosen Maine residents from April 5 to April 12, 2000. The sampling error associated with this survey is plus or minus 5%. The results of this survey are considered representative of the adult age population of Maine as a whole.

"Mainers who do not have insurance or those who have high prescription drug expenses are particularly concerned about the cost of prescription drugs, but virtually all Mainers favor government involvement in influencing or controlling costs", commented Curtis Mildner, President of Market Decisions.

"We were surprised to see that Mainers who had insurance or did not see the cost of prescription drugs as a hardship also favored a government role in influencing or regulating prescription drug prices", said Dr. Brian Robertson, Research Director at Market Decisions.

Prescriptions are a major expenditure for many Maine households.

How much did your household spend on prescription drugs during the past 3 months?	Percentage of Population
None	19%
\$1-49	21%
\$50-99	15%
\$100-199	15%
\$200-499	13%
\$500 or more	8%
Don't Know/Refused	7%

- Maine households paid an average of \$118 during the past 3 months for prescriptions – an average of \$39 per month.

Nearly three out of four Mainers support an active government role in controlling drug prices.

Would you support the idea of the state setting a maximum for drug prices through a governmental agency?	% of Respondents
YES	72%
NO	19%
Don't Know/Refused	8%

- Again, women were more likely to favor efforts to control pricing. Seventy-six percent of female respondent indicated they would support the idea of the state setting a maximum for drug prices, compared to only 69% of male respondents.
- Support for the state setting drug prices was higher among those who were currently NOT covered by health insurance. It was also higher among those indicating the cost of prescription drugs was a burden on their household.

Lower Income Mainers are more likely to see the cost of drugs as a hardship

Annual Household Income	% Indicating cost of drugs was a hardship
< \$10,000	42%
\$10,000 - \$20,000	38%
\$20,000 - \$30,000	35%
\$30,000 - \$40,000	23%
\$40,000 - \$50,000	9%
\$50,000 - \$60,000	14%
\$60,000 - \$70,000	6%
\$70,000 - \$80,000	0%
\$80,000 - \$90,000	11%
> \$90,000	7%

- The percentage of respondents who indicated the cost of prescription drugs was a burden generally decreased with income.

Mainers strongly support a government role in negotiations to reduce drug prices.

Would you support the idea of the state negotiating drug prices in cooperation with other New England states with the aim of lowering prices?	% of Respondents
YES	92%
NO	5%
Don't Know/Refused	3%

- Support for this idea is strong across all ages and incomes.
- Women were more likely than men to support the idea, though over 90% support the idea among both genders. Ninety-seven percent of women indicating they would support this idea. This compares with 91% of male respondents.
- Support for this idea is not affected by whether or not a respondent has health insurance.

- Some 8% of Maine residents paid more than \$500 during the past 3 months on prescriptions.

Average amount spent of prescriptions during the past three months by age of respondent.

Age	Amount spent in past 3 months
18-29	\$60
30-39	\$72
40-49	\$133
50-59	\$110
60+	\$192

- Average expenditures on prescriptions generally increased with age

Many Mainers see the cost of prescriptions as a hardship

Overall, is the cost of prescription drugs a hardship for you and your household?	% of Respondents
YES	23%
NO	76%
Don't Know/Refused	1%

- Respondents who see the cost of prescriptions as a hardship paid an average of \$240 during the 3 months, those who do not see this as a hardship paid an average of \$84 during the past 3 months.

Mainers without health insurance are more likely to see the cost of prescription drugs as a hardship

Are you covered by any type of health insurance?	Yes	No
	87%	12%
Is the cost of drugs a hardship?		
Yes	20%	43%
No	79%	55%

- Some 43% of those without health insurance see the cost of drugs as a hardship as compared with 20% of those who have health insurance.
- Women were more likely than men to consider the cost of prescription goods a burden on the household than men (29% compared to only 18% of male respondents)
- The percentage of respondents indicating cost was a burden increased with age. While 18% of respondents age 18 to 29 indicated the cost of prescription drugs was a burden on their household, this percentage was 36% among those 60 and older.

Press Release

FOR IMMEDIATE RELEASE
MAY 10, 2000

CONTACT: SEN. PINGREE
OR ALLISON LAZOS,
(207) 287-1515

Legislators and Governor Announce Compromise on Prescription Drug Fair Pricing Bill

(Augusta) – Senator Chellie Pingree (D-Knox), lead sponsor of the bill, announced Wednesday a compromise on LD 2599, *An Act to Establish Fairer Pricing for Prescription Drugs* has been reached between legislators and the Governor. The bill was pulled back from the Governor's desk when it became apparent that a veto was inevitable. The legislative recess has given an opportunity to craft a bill that could be enacted into law.

"Everyday Maine legislators hear from senior citizens who tell us they have to choose – do they take the medication their doctor prescribed, or buy food for the table? The problem is clear – life saving prescription drugs cost too much in America, yet we can step across the border into Canada, where the same drug is half the price.

The high cost of prescription drugs is a serious problem in Maine. I am very happy we were able to reach a compromise with the Governor's office. The bill being presented to the full legislature will provide the citizens of Maine immediate relief and time to negotiate down the excessive price of prescription drugs to an affordable and accessible level.

We have taken a bold stand. Our actions give courage to other states and put pressure on the federal government to do the right thing. The pharmaceutical industry is not being fair when they expect Americans to fund their very high profits, while the rest of the world receives big discounts. The government, from Maine to Washington D.C., has a responsibility to negotiate on the behalf of our citizens.

Mainers are depending on us and the world is watching us to make sure we do not back down. I am grateful to all the Maine lawmakers and the Governor who have shown the courage to stand up for our citizens," Pingree stated.

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