Amend the bill by striking out everything after the enacting clause and before the summary and inserting the following:

'**Sec. 1. 22 MRSA §2700, sub-§5,** as amended by PL 2005, c. 297, §1 and affected by §3, is further amended to read:

5. Unused Pharmaceutical Disposal Program Fund; funding. The Unused Pharmaceutical Disposal Program Fund, referred to in this chapter as "the fund," is established within the agency to be used by the director of the agency to fund or assist in funding the program and programs under Title 38, section 1611. Any balance in the fund does not lapse but is carried forward to be expended for the same purposes in succeeding fiscal years. The fund must be deposited with and maintained and administered by the agency. The agency may accept funds into the fund from any non-General Fund source, including grants or contributions of money, fines and penalties imposed pursuant to Title 38, section 1611, subsection 13 or other things of value, that it determines necessary to carry out the purposes of this chapter. Money received by the agency to establish and maintain the program must be used for the expenses of administering this chapter and Title 38, section 1611 and to support the expenses of programs established under Title 38, section 1611 for the collection, handling, transportation, management and disposal of unwanted covered drugs obtained from residential sources.

Sec. 2. 38 MRSA §1611 is enacted to read:

§ 1611. Disposal of unwanted drugs

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

A. "Agency" means the Department of Public Safety, Maine Drug Enforcement Agency under Title 25, section 2955.

B. "Covered drug" means all prescription drugs and nonprescription over-the-counter drugs and veterinary drugs obtained from residential sources in any form, including pill, tablet, capsule, suppository, liquid, cream, ointment, lotion, transdermal patch, powder or aerosol form and both brand name and generic drugs but not including vitamins, herbal-based remedies, human shampoos, cosmetics or toothpaste or pet pesticide products contained in pet collars, powders or shampoos.

C. "Manufacturer" means a person or entity that:

(1) Has a physical presence in the United States and causes a covered drug to be manufactured or has legal ownership of the brand, brand name or co-brand under which a covered drug is sold;

(2) Imports a covered drug branded or manufactured by a person or entity that has no physical presence in the United States; or

(3) Sells at wholesale a covered drug and does not have legal ownership of the brand or brand name, but elects to fulfill the manufacturer's responsibilities for that covered drug.

"Manufacturer" does not include a retailer that puts its store label on a covered drug unless the retailer imports the covered drug directly from a person that has no physical presence in the United States.

D. "Program" means a program established by a manufacturer or in conjunction by manufacturers pursuant to this section for the collection, handling, transportation, management and disposal of unwanted covered drugs.

E. "Residential source" includes single-family and multiple-family residences and locations where unwanted covered drugs may be found such as hospice facilities, nursing homes, boarding homes, schools, foster care facilities, day care facilities, correctional facilities and other locations where either people or their pet animals, or both, reside on a temporary or permanent basis. "Residential source" does not include a hospital, a pharmacy or a business such as a physician's office or any other nonresidential source identified by the department.

F. "Unwanted covered drug" means a covered drug that its owner no longer wants or that has been abandoned or discarded or is intended to be discarded by the owner.

G. "Wholesaler" means a person or entity that buys a covered drug for resale and distribution to persons or entities other than consumers but that does not have legal ownership of the brand or brand name.

2. Requirement; limitation. Effective January 1, 2011, a manufacturer of covered drugs sold in the State:

A. Shall participate in a program for the collection, handling, transportation, management and disposal of unwanted covered drugs in accordance with this section; and

B. May not engage in the collection of unwanted covered drugs in the State prior to receiving approval from the department for operation of a program for the collection, handling, transportation, management and disposal of those drugs.

3. Manufacturer responsibility. A manufacturer of covered drugs sold in the State shall participate in a program, individually or in conjunction with other manufacturers, for the collection, handling, transportation, management and disposal of unwanted covered drugs. A manufacturer that operates a program independently shall ensure that the program operates in compliance with the provisions of this section, in accordance with the approval issued by the department under subsection 7 and in compliance with other state and federal law. A manufacturer that participates in a program with other manufacturers shall ensure that the program in which it participates operates in compliance with the provisions of this section, in accordance with the approval issued by the department under subsection 7 and in compliance with other state and federal law.

A. By October 1, 2010 a manufacturer of covered drugs sold in the State shall submit to the department an application as set out in subsection 5 to operate the manufacturer's program, individually or in conjunction with other manufacturers.

B. Before initiating sales of covered drugs in the State, a manufacturer of covered drugs to be sold in the State after October 1, 2010 shall submit an application as set out in subsection 5 to operate a program to the department or join a program approved under subsection 7.

C. A manufacturer whose application for a program has been approved under subsection 7 shall begin operating the program within 90 days of obtaining approval from the department.

D. A manufacturer or manufacturers that participate in a program shall pay all the administrative and operational costs associated with implementation of a program, including the cost of the collection, transportation, management and disposal of the unwanted covered drugs and the recycling or disposal of the related packaging. For calendar years 2011, 2012 and 2013, ongoing program administrative costs are capped in accordance with the procedures in subsection 11.

E. A manufacturer or manufacturers that participate in a program may not charge a fee at the time of sale of the covered drugs or at the time the unwanted covered drugs are delivered or collected for disposal.

4. Program component requirements. A program must include the following component requirements:

A. The program must collect unwanted covered drugs from all manufacturers. The collection system must be convenient and adequate to serve the needs of residents in both urban and rural areas;

B. The program must transport, handle, manage and dispose of unwanted covered drugs from all manufacturers. The unwanted covered drugs must be disposed of in compliance with the requirements of subsection 6; and

C. The program must include a public education and communications strategy that includes educational and outreach information and materials provided at no cost to consumers, pharmacies, health care facilities and other interested parties. The public education and communications strategy must:

(1) Promote the use of the program and the proper disposal of unwanted covered drugs so that collection options are widely understood by consumers, pharmacists, retailers of covered drugs and health care practitioners including doctors and other prescribers;

(2) Provide a toll-free telephone number and publicly accessible website where information regarding collection options is made available; and

(3) Describe where and how to return unwanted covered drugs.

5. Application requirements. A program application submitted to the department under subsection 3, paragraph A or B must:

A. List all manufacturers participating in the program and the manufacturers' contact information;

B. List the hazardous waste disposal facilities and other entities, and their contact information, to be used to collect and destroy the unwanted covered drugs;

C. Describe the policies and procedures to be followed by persons in charge of unwanted covered drugs collected pursuant to the program;

D. Describe how the collected unwanted covered drugs are tracked through to final disposal and how safety and security are maintained;

E. Describe a means to allow for access to collected unwanted covered drugs for research purposes by an entity that has been approved by the department, agency or Department of Health and Human Services for a research project;

F. Describe a method that can be used to conduct probability sampling and analysis to achieve an unbiased and statistically significant data set on each unwanted covered drug returned, including, but not limited to, the brand or generic name of the returned drug, its strength or concentration, the quantity returned and the quantity prescribed or included in the original purchase if known; and

G. Include a description of the program's components required under subsection 4.

6. Drug disposal. A program must provide for the disposal of all unwanted covered drugs at a hazardous waste incinerator, as defined in section 1303C, subsection 15A, except that a manufacturer may petition the department for, and the department may grant, approval to use an alternative disposal technology that provides superior environmental and human health protection to that provided by hazardous waste incineration if the alternative technology is proven and available. The department shall inform the agency of its determination on a petition under this subsection and may grant the petition only if the agency concurs. Alternative technology under this subsection must provide equivalent protection in each, and superior protection in one or more, of:

A. The monitoring of any emissions or waste;

B. Worker health and safety;

C. Air, water or land emissions contributing to persistent, bioaccumulative and toxic pollution; and

D. The overall environment and human health.

7. Program review and approval. The department shall review each application submitted pursuant to subsection 3 after consultation with the agency and the Department of Health and Human Services.

A. If the department is satisfied that an application is complete and that a program complies with the requirements of this section, the department shall issue an approval or an approval with modifications.

B. If a program is rejected, the department shall provide the applicant with the reasons for rejecting the program in writing.

C. The department shall provide expedited review and approval for a program submitted by a manufacturer independently for a single covered drug that is subject to a mandatory drug return procedure by the United States Department of Health and Human Services, Food and Drug Administration. The expedited review and approval must require that the manufacturer file with the department an application and information on the quantities of the covered drug dispensed within the State and quantities returned from within the State under the Food and Drug Administration procedure and other information determined to be necessary by the department. Information reported under this paragraph is confidential and may not be disclosed by the department, except that the department may share that information with the Department of Health and Human Services and the agency.

D. The decision of the department under this subsection is a final decision and may be appealed to the Board of Environmental Protection pursuant to section 341D, subsection 4.

8. Program modification. Except as provided in this subsection, a program must be operated in compliance with the approval issued by the department under subsection 7. A manufacturer or manufacturers operating the program may make substantive changes to the manner in which the program is operated only upon submission of a written application for modification to and issuance of a notice of written approval by the department. The manufacturer or manufacturers operating the program may request a substantive change to the previously approved program at any time. The following changes are not substantive and may be made without prior notice and approval:

A. Additions and changes to the list of hazardous waste facilities and other entities under contract for drug collection or destruction under subsection 5, paragraph B may be made without the department's prior written approval. The manufacturer or manufacturers operating the program shall inform the department of such an addition or change 15 days prior to the effective date of the addition or change. If there is no objection by the department, the manufacturer or manufacturers operating the program may implement the addition or change;

B. An additional manufacturer may participate in a program if:

(1) The additional manufacturer provides notice to the department within 3 days of beginning participation in the program; and

(2) The manufacturer or manufacturers operating the program provide the department with an updated manufacturer participant list under subsection 5, paragraph A within 15 days after an additional manufacturer begins participation in the program; and

C. If a manufacturer withdraws from a program operated with other manufacturers or discontinues a program operated independently, the manufacturer shall provide notice to the department within 15 days prior to taking action and a statement explaining the manufacturer's plans for complying with this section.

9. Enforcement. If the department determines that a program is not being operated in accordance with this section or any rules adopted under this section or if the department determines that there is an imminent danger to the public, the provisions of this subsection apply.

A. The department may amend the approval of the program by clarifying terms or conditions to ensure full implementation of the program or suspend or cancel the approval of the program. Except as provided in paragraph B, at least 15 days prior to amending, suspending or canceling an approval, the department shall inform the manufacturer or manufacturers operating the program of the action and provide the manufacturer or manufacturers an opportunity to respond.

B. If the department determines that it is necessary in order to protect the public from imminent danger, the department may immediately amend, suspend or cancel the approval of a program without giving the manufacturer or manufacturers operating the program an opportunity to be heard, but shall give that manufacturer an opportunity to be heard through proceedings consistent with Title 5, chapter 375, subchapter 4 within 15 days after the date on which the department takes action.

10. Program reports. A manufacturer or manufacturers operating a program approved under subsection 7 shall provide program reports as follows.

A. By February 1, 2012, and annually thereafter, the manufacturer or manufacturers operating the program shall submit to the department, the Department of Health and Human Services and the agency a written annual report in a format prescribed by the department covering the previous calendar year. The program report must include:

(1) A list of manufacturers participating in the program and the manufacturers' contact information;

(2) Documentation verifying collection and disposal of the unwanted covered drugs;

(3) A list of the hazardous waste disposal facilities used, the location of those facilities and the weight of unwanted covered drugs collected and disposed of at each facility;

(4) A statement of whether policies and procedures for transporting and disposing of unwanted covered drugs, as established in the program, were followed during the year and a description of noncompliance with those policies and procedures, if any;

(5) A statement of whether any safety or security problems occurred during collection, handling, transportation, management or disposal of unwanted covered drugs during the year and, if so, what changes are proposed for policies, procedures or tracking mechanisms to improve safety and security in the future;

(6) A description of the public education effort and communications strategy under subsection 4, paragraph C implemented during the year;

(7) A description of research, if any, regarding hazardous waste disposal techniques that provide superior protection to human health and the environment beyond that provided by current disposal techniques;

(8) A description of actions the program will take to increase public awareness if the program evaluation required under subsection 12 indicates that less than 75% of adults in the State are aware of the program and how to participate in it; and

(9) Any other information that the department, the Department of Health and Human Services and the agency may reasonably require.

B. By August 1, 2011, and every 6 months thereafter, the manufacturer or manufacturers operating the program shall submit to the department a data report of the amount, by weight, of unwanted covered drugs collected during the prior 6 months.

11. Program costs. In calendar years 2011, 2012 and 2013, the commissioner shall approve the suspension, in whole or part, of a program approved under subsection 7 if the manufacturer or manufacturers operating the program demonstrate to the commissioner's satisfaction that the aggregate program costs directly attributable to collection and disposal of unwanted covered drugs will or are expected to exceed $1,500,000 for the year. If the annual direct costs of collecting and disposing of unwanted covered drugs are not expected to exceed $1,250,000, the manufacturer or manufacturers shall provide up to $150,000 for data gathering and analysis if requested by the Department of Health and Human Services. Direct costs are those ongoing administrative costs that are necessary for the day-to-day operation of the program such as administrative salaries, the purchase of supplies, drug handling and disposal costs and the creation of educational materials. Direct costs do not include one-time program development expenditures or costs for legal advice or lobbying. Beginning in calendar year 2014, the $1,500,000 cap is abolished and the manufacturers are responsible for paying actual total costs incurred to implement the program as approved.

12. Program evaluation. The manufacturer or manufacturers operating a program shall conduct a survey to determine public awareness of the program using a survey tool approved by the department in consultation with the agency and the Department of Health and Human Services. The initial survey must be conducted during March 2011, and survey results must be submitted to the department by June 1, 2011. Follow-up surveys must be conducted and survey results must be reported on the same

schedule annually until the survey results indicate that more than 75% of adults in the State are aware of the program and how to participate in it. The department may require that the survey tool be modified and updated as appropriate.

13. Fines and penalties. After January 1, 2011, a manufacturer that is not in compliance with this section is subject to civil penalties under section 349. By June 1, 2011 the department shall list on its publicly accessible website manufacturers that are participating in approved programs and manufacturers that have been identified as being not in compliance with this section. All penalties and fines collected for violations of this section must be deposited into the Unused Pharmaceutical Disposal Program Fund established under Title 22, section 2700, subsection 5.

14. Wholesaler responsibility. By February 1, 2012, and annually thereafter, a wholesaler of covered drugs sold in the State shall report to the department the name and contact information for each manufacturer whose covered drugs the wholesaler sold or distributed within the State during the previous calendar year and the total aggregate amount of revenue to the wholesaler generated from those sales. Information reported under this subsection is confidential and may not be disclosed by the department except that the department may share that information with the Department of Health and Human Services and the agency.

15. Pharmacy responsibility. A pharmacy licensed to operate in the State under Title 32, chapter 117 shall make available to its customers the educational information and materials provided by programs under subsection 4, paragraph C and, if a program approved under subsection 7 supplies prepaid mailing envelopes, shall provide the prepaid mailing envelopes to its customers.

16. Report to the Legislature. By March 15, 2011, and annually thereafter, the department, in consultation with the agency and the Department of Health and Human Services, shall report to the joint standing committees of the Legislature having jurisdiction over health matters and environmental matters concerning the status of a program established pursuant to this section and shall recommend such modifications to this section as the department, the Department of Health and Human Services and the agency determine necessary or appropriate. The report in 2015 must include a recommendation on continuing the semiannual reports required by subsection 10, paragraph B.

17. Rules. The department may establish rules to implement this section. Rules adopted pursuant to this subsection are routine technical rules as defined in Title 5, chapter 375, subchapter 2A.

Sec. 3. Stakeholder group. The Department of Environmental Protection shall convene a diverse stakeholder group that includes representatives of the Department of Public Safety, Maine Drug Enforcement Agency; the Department of Health and Human Services; the Department of Environmental Protection; and consumers, manufacturers, retail pharmacies, law enforcement agencies, health organizations and environmental groups to review and advise the Department of Environmental Protection regarding the implementation of any unwanted covered drug disposal program established pursuant to the Maine Revised Statutes, Title 38, section 1611. The stakeholder group shall make recommendations regarding rulemaking by the Department of Environmental Protection and program

implementation. The recommendations of the stakeholder group must be included in the initial report of the Department of Environmental Protection to the joint standing committees of the Legislature pursuant to Title 38, section 1611, subsection 16.

Sec. 4. Enforcement of unwanted drug disposal program. The Department of Environmental Protection shall develop noncompliance response and enforcement guidance that is appropriate for the implementation of the unwanted covered drug disposal program under the Maine Revised Statutes, Title 38, section 1611 that is consistent with guidance across the department, including letters of warning, notices of violation and administrative consent agreements.

Sec. 5. Appropriations and allocations. The following appropriations and allocations are made.

PUBLIC SAFETY, DEPARTMENT OF

Drug Enforcement Agency 0388

Initiative: Provides funding to administer drug manufacturer programs for the collection, handling, transportation, management and disposal of unwanted covered drugs.

OTHER SPECIAL REVENUE FUNDS	**2009-10**	**2010-11**
All Other	$0	$150,000
OTHER SPECIAL REVENUE FUNDS TOTAL	$0	$150,000

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SUMMARY

This amendment is the majority report of the committee. The amendment replaces the bill. It retains the original purpose of the bill: to require manufacturers of drugs to participate in programs for the collection, handling, transportation, management and disposal of unwanted drugs from residential sources. It pushes back the beginning date for the program and corresponding compliance and reporting dates to provide more start-up time. It more specifically defines "manufacturer" and "covered drug." Retailers are excluded from the definition of "manufacturer," and certain personal care products and pet pesticide products contained in pet collars, powders or shampoos are excluded from the definition of "covered drug." It adds correctional facilities to the definition of "residential sources." It requires that manufacturers report data on drugs returned to the Department of Environmental Protection, Department of Health and Human Services and Department of Public Safety, Maine Drug Enforcement Agency. It requires the application for the program to include a method for conducting probability sampling and analysis and a means to allow access to the collected drugs for research purposes. It clarifies manufacturer responsibilities, program requirements, application requirements, procedures and appeal rights. The amendment allows revenues from fines and penalties to be used to support the costs of programs operated by the manufacturers. The amendment requires wholesalers to report the names of manufacturers whose covered drugs the wholesaler sells or distributes in the State, beginning in 2012. The amendment requires

annual reporting to the joint standing committees of the Legislature having jurisdiction over health matters and environmental protection matters. It requires the establishment of a stakeholder group to advise the Department of Environmental Protection regarding rulemaking and implementation of the program. It also adds provisions requiring the Department of Environmental Protection to develop appropriate noncompliance response and enforcement guidance.

FISCAL NOTE REQUIRED
(See attached)