HOUSE BILL REPORT
HB 1165

As Reported by House Committee On:
Environmental Health
General Government Appropriations

Title: An act relating to providing safe collection and disposal of unwanted drugs from residential sources through a producer provided and funded product stewardship program.

Brief Description: Providing for the safe collection and disposal of unwanted drugs from residential sources through a producer provided and funded product stewardship program.

Sponsors: Representatives Morrell, Campbell, Priest, Dickerson, Hudgins, Rodne, Cody, Nelson, Chase, O'Brien, Dunshee, Kenney, Wood, Hunt, McCoy, Upthegrove, Hasegawa, Anderson, Appleton, Pedersen, Hunter, Darneille, Roberts, Rolfes, White, Kagi, Ormsby, Conway, Orwall, Simpson, Goodman, Van De Wege and Santos.

Brief History:
Committee Activity:
Environmental Health: 1/21/09, 1/28/09 [DPS];
General Government Appropriations: 2/17/09, 2/26/09 [DP2S(w/o sub ENVH)].

Brief Summary of Second Substitute Bill

- Requires that the producers of unwanted medicines sold in Washington create and fund product stewardship programs to collect unwanted medicines from consumers and dispose of them at hazardous waste facilities.
- Requires that all producers participate in a product stewardship program with a plan approved by the Board of Pharmacy by January 1, 2012.

HOUSE COMMITTEE ON ENVIRONMENTAL HEALTH

Majority Report: The substitute bill be substituted therefor and the substitute bill do pass. Signed by 6 members: Representatives Campbell, Chair; Chase, Vice Chair; Dickerson, Dunshee, Hudgins and Rolfes.

Minority Report: Do not pass. Signed by 4 members: Representatives Shea, Ranking Minority Member; Orcutt, Assistant Ranking Minority Member; Finn and Kretz.

This analysis was prepared by non-partisan legislative staff for the use of legislative members in their deliberations. This analysis is not a part of the legislation nor does it constitute a statement of legislative intent.

Staff: Pam Madson (786-7111)

Background:

Consumers have unused medicines in their homes for a variety of reasons. These medicines can pose risks and, if not disposed of properly, can contribute to the contamination of the water supply and can result in accidental poisoning and drug abuse. Consumers dispose of drugs by throwing them in the garbage, flushing them down the toilet or sink, or returning them to their pharmacy. Guidance to consumers on how to properly dispose of unused medications is inconsistent.

A variety of medicine-return programs are appearing throughout the country. They use methods that allow consumers to return unused and unwanted drugs such as permanent return locations, one-day return opportunities, and mail-back or ship-back of drugs.

The Department of Ecology (DOE) and local governments implement solid waste disposal and hazardous waste disposal programs. The State Board of Pharmacy (Board) licenses health care professionals who are authorized to prescribe and administer drugs.

Summary of Substitute Bill:

A program that allows consumers to return unwanted legend and non-legend drugs is established. By January 1, 2012, all drug producers of drugs sold in the State of Washington must participate in a drug return program. Producers of the drugs are responsible for planning and administering the program.

Product Stewardship Program.
The elements of a producer administered program include:

- All costs for collecting, transporting, and disposing of unwanted drugs must be paid by the producer.
- No fee may be imposed by the program on the consumer either when the drugs are purchased or when they are delivered for collection.
- A program must allow collection of drugs regardless of whether the producer is a participant in the program.
- A producer program must develop a plan that is approved by the DOE.
- A program may include one or more producers or may be an organization that manages the program for producers.

Product Stewardship Plan.
The plan must contain provisions for:

- a collection system;
- a transportation and drug disposal system;
- the secure tracking and handling of the drugs;
- public education and outreach efforts of the program; and
- how packaging collected with the drugs will be recycled.

A product stewardship plan must be approved by the DOE. The initial plans must be completed by January 1, 2011. The plan must be updated at least every four years. Any changes to the plan must obtain prior approval with limited exceptions.

Annual Report.
Beginning in 2013 each program must submit an annual report to the DOE. The report includes:

- information on the amount of product collected and processed through a disposal facility; and
- penalties or violations received by participating transporters and disposal facilities.

Promotion of the Program.
The program must make the public aware of the efforts to collect unwanted residential drugs through web sites, toll-free telephone numbers, and promotional materials located in pharmacies and other appropriate locations.

Disposal of Unwanted Drugs.
All unwanted drugs must be disposed of at a hazardous waste facility.

Changes to the Plan by the Government Agency.
If the DOE determines that there is imminent danger to the public because of operation or provisions of the product stewardship plan, it may amend, suspend, or cancel approval of a plan.

Enforcement - Producers.
Enforcement begins with written warnings prior to imposing any monetary penalty. The DOE may waive or reduce the penalty. Penalties include:

1. *Producer not participating in an approved program*. After receiving a written warning, if the violation continues, the DOE shall impose a monetary penalty of $10,000 for each calendar day the violation continues.

2. *Producer fails to implement its approved plan*. After receiving a written warning, if the violation continues, the DOE shall impose a monetary penalty of $5,000. After 30 days and for each 30-day period the violation continues, the monetary penalty increases to $10,000.

3. *Failure to update a plan, submit a required report, or provide the required notification*. After a written warning, a monetary penalty of $5,000 must be imposed. After 30 days, and for each 30-day period the violation continues, the monetary penalty increases to $10,000.

Enforcement - Wholesalers.
Enforcement begins with written warnings prior to imposing any monetary penalty. Wholesalers who sells drugs from a producer not participating in a product stewardship program or whose program is not in compliance with the law are subject to a monetary penalty of $10,000. The DOE must maintain a website indicating whether a producer is in compliance.

Rule-making and Reporting to the Legislature.
The DOE may adopt rules to implement the law and must consult with the Board on rules dealing with the secure collection, tracking, and handling of drugs collected under the program. The DOE may establish performance standards for the product stewardship program. By December 31, 2014, the DOE must report to the Legislature on the implementation of this law.

Funding. The DOE may establish fees for administering the program to fully recover but not exceed the expenses incurred. The Pharmaceutical Product Stewardship Program Account is established. All fees and penalties are deposited into the Pharmaceutical Product Stewardship Program Account. Money may be loaned from the State Toxics Control Account to pay initial administrative costs but must be repaid with interest within two years of a loan of funds.

Substitute Bill Compared to Original Bill:

The substitute bill removes discretionary penalty assessment authority by the DOE under the enforcement provisions and specifies the amount of a penalty for specific violations. The definition of "producer" no longer includes retailers who elect to act as producers or retailers who place a store label on a covered product. The substitute bill confirms that controlled substances dispensed by prescription or restricted to use by practitioners are covered products under the bill. The purpose for which moneys can be loaned from the State Toxics Control Account is limited to the initial administration of the program. Money may not be loaned "from time to time" for this purpose.

Appropriation: None.

Fiscal Note: Available.

Effective Date of Substitute Bill: The bill takes effect 90 days after adjournment of the session in which the bill is passed.

Staff Summary of Public Testimony:

(In support) People have a number of unused drugs at home in their medicine cabinet and they do not know what to do with them. When a family member dies, people want to know where medications can be taken. Medications must be disposed of properly. Medications save lives and the pharmaceutical industry is a very important industry. Producers must be allowed to design the program that works best for them. Drug companies advertise directly to the public. There is a responsibility on their part to help dispose of unused drugs properly.

This bill offers a precautionary approach rather than waiting for the bad consequences to occur. The best principle is to prevent the harm from occurring in the first place rather than have to fix the damage already caused. The environmental concern is for contamination of water supplies and leaching of drugs out of landfills. Drugs that are thrown out as garbage

should not go to a regular landfill but to a regulated hazardous waste landfill. There are other sources of contamination of the environment from drugs including drugs that are metabolized and pass through the human body.

This is not just an environmental bill. There is a risk that medicines are used by young people who can abuse the drugs and overdose on them. There is a street value to drugs that are available in family medicine cabinets. People need a safe place to dispose of unwanted medications.

The DOE has experience in take-back programs. The Board also has a role. A similar bill passed out of committee last year. Funding from the Model Toxics Control Account (MTC Account) is a loan to the DOE. The MTC Account has funded the pilot program currently operating. This is a producer-pay take-back program. Taxpayers should not pay for this program.

Group Health Cooperative and Bartell Drug Stores, along with local governments and nonprofit organizations, are participating in a pilot program to take back medicines. There is a need for a statewide program with sustainable funding. There is precedent for producer responsibility programs. An example is the recently operational electronic products take back program. British Columbia has operated a producer take-back drug program for a number of years. It is an industry-run program supported by producers. Cost of medicines did not increase in British Columbia. Many companies impacted by this bill are paying into the British Columbia program. The British Columbia program shows a program can be run by manufacturers.

(With concerns) There is concern over using money from the MTC Account. The MTC Account is currently over-subscribed. There is much more cleanup to be done that is paid for by the MTC Account. The MTC Account fund source is very volatile because it is based on the wholesale price of oil. The Federal Drug Enforcement Administration (DEA) prohibits anyone other than authorized DEA agents or law enforcement to take back controlled substances. Controlled substances cannot be part of this bill. There is concern about retailers who have store brands incurring costs under this program. Now is not the time to impose more costs on businesses.

(Information only) Washington Policy Center released a study in January based on this legislation last year and the Puget Sound Action Agenda. There are three questions that haven't been answered and can't be at this time. What is the cause and source of the trace elements? They are human sources, but are they from unwanted drugs or people secreting them? What amounts of drugs go unused or unwanted? There is no hard science to definitively answer this question. What are the costs and benefits of diverting resources to these programs versus providing appropriate attention to identified solutions? As an example, in the context of the Puget Sound Partnership, resources would be better used to open up habitat than to take back drugs. In 2007 federal agencies put out information on how to dispose of unwanted drugs. If the three questions cannot be answered, the approach taken by the federal regulators should be used.

(Opposed) The industry is committed to patient safety and environmental health. It has been looking at drug diversion for a number of years. Prescription medicines once they get to

patients cannot be recycled. If they are not used they must be disposed of. Patients should be encouraged to use their medicine. They should only get small samples to see if the medications will work. Disposal should not increase the risk of diversion, harm to workers, or harm to the environment. They should be disposed of in properly regulated landfills.

Most drugs get into the environment through human metabolism. A small percentage of drugs get into the environment from the disposal of unwanted drugs. People should put them in a sealed container to make them unattractive to those who might try get a hold of them. Using kitty litter or coffee grounds helps to do that. Medicines collected at collection sites are at more risk of diversion or harm to workers handling the drugs. A container at drug stores is an attractive nuisance and could be vulnerable to diversion of drugs. Because of the possibility of controlled substances coming into collection sites, there must be a law enforcement officer or a DEA officer present. The better approach is to educate consumers on how to dispose of drugs properly in landfills.

Science does not support the mandate of this program over consumer education programs. These voluntary programs are more convenient to consumers in their homes and makes it more likely people will do it. There are many producers, and that could generate a burdensome number of plans to be approved by the DOE. The industry has worked to address these problems. A national plan is a better approach. This type of program is premature. There is no evidence that the British Columbia model has led to a decrease in any of the problems this proposal is supposed to address. The carbon footprint of a take-back program is much larger than a landfill program. Landfill disposal is a more environmentally friendly disposal method. Now is not the time to impose more cost on employers.

Persons Testifying: (In support) Representative Morrell, prime sponsor; Dr. Robert Day, Science and Management of Addictions Foundation; Ruth Shearer, Washington Senior Citizen Lobby; Dan Connolly, Bartell Drugs; Ken Butti, LOTT Alliance; Suellen Mele, Washington Citizens for Resource Conservation; Pam Badger, King County Solid Waste; Margaret Shield, Local Hazardous Waste Management Program; Lisa Butler, Washington State Hospice and Palliative Care Organization; Heather Trim, People for Puget Sound; Steve Zemke, King County Democrats; Elizabeth Davis, League of Women Voters of Washington; Scott DePuy, Ryans Solution Foundation; and Dr. Shirley Reitz, Group Health Cooperative.

(With concerns) Lis Houchen, National Association of Chain Drug Stores; Mark Johnson, Washington Retail Association; and Tammy Fellin, Association of Washington Cities.

(Information only) Brandon Houskeeper, Washington Policy Center.

(Opposed) Jeff Gombosky, Amgen; Marjorie Powell, Pharmaceutical Research and Manufacturers of America; Ashlen Anderson, Consumer Healthcare Products Association; and Grant Nelson, Association of Washington Business.

Persons Signed In To Testify But Not Testifying: None.

HOUSE COMMITTEE ON GENERAL GOVERNMENT APPROPRIATIONS

Majority Report: The second substitute bill be substituted therefor and the second substitute bill do pass and do not pass the substitute bill by Committee on Environmental Health. Signed by 8 members: Representatives Darneille, Chair; Dunshee, Hudgins, Kenney, Pedersen, Sells, Van De Wege and Williams.

Minority Report: Do not pass. Signed by 6 members: Representatives Takko, Vice Chair; McCune, Ranking Minority Member; Hinkle, Assistant Ranking Minority Member; Armstrong, Blake and Short.

Staff: Owen Rowe (786-7391)

Summary of Recommendation of Committee On General Government Appropriations Compared to Recommendation of Committee On Environmental Health:

The approving agency is changed from the Department of Ecology to the Board of Pharmacy (Board), and requires that the product stewardship programs for unwanted drugs from residential sources be licensed by the Board. Product stewardship plans must include a description of how patient information on drug packaging will be secure during collection, transportation, and disposal of the drugs. Hospitals are exempt from the application of this bill, and a clarification is made that compounding pharmacists are not considered producers under the bill. The penalty for drug wholesalers who sell products in Washington from producers who are not participating in a licensed product stewardship program is removed, but wholesalers are required to provide a list to the Board of producers of products they sell, and update the list by January 15, of each year.

Appropriation: None.

Fiscal Note: Available.

Effective Date of Second Substitute Bill: The bill takes effect 90 days after adjournment of the session in which the bill is passed.

Staff Summary of Public Testimony:

(In support) The fiscal note will be reduced significantly by moving the product stewardship program from the Department of Ecology to the Board of Pharmacy. It is necessary to create a drug disposal program in order to lessen the amount of overdoses and accidental poisonings. School resource officers are seeing an increase in the usage of prescription drugs taken from family members. This bill is intended to reduce accidents, drug abuse, and water contamination. This bill gives the drug manufacturers the flexibility to tailor a program that suits their needs and is as cost effective as possible. The bill is budget-neutral to the state because the state's cost would be recovered by fees to producers and the initial loan from the State Toxics Account would be paid back within two years. If producers choose to pass the cost of the drug disposal program onto consumers, it would only be a penny or two on each container of medicine.

(With concerns) While the intent of this bill is to pass the cost of drug disposal to producers, the end result is restricting access of pharmaceuticals to consumers. The drug companies

will pass the cost of this program onto consumers. Producers could potentially withdraw from the marketplace. There is no science to support the impact of programs like these on drug abuse or environmental protection.

(Opposed) The industry has already voluntarily created point of sale brochures to educate the public about the appropriate disposal of drugs. There is no science that supports drug disposal programs impact on reducing drug abuse or on protecting the environment. Why would the state want to buy a program where there is no data to support outcomes? The education of consumers is the place to start, this approach is premature.

Persons Testifying: (In support) Representative Morrell, prime sponsor; Pat Slack, Snohomish County Drug Task Force; and Suellen Mele, Washington Citizens for Resource Conservation.

(With concerns) Brandon Houskeeper, Washington Policy Center.

(Opposed) Jeff Gombosky, Pharmaceutical Research and Manufacturers of America; and Grant Nelson, Association of Washington Business.

Persons Signed In To Testify But Not Testifying: None.