SENATE BILL REPORT

SJM 8007

AS OF FEBRUARY 19, 1993

Brief Description: Petitioning Congress and the President to authorize the Federal Food and Drug Administration to study a transitional nonprescription drug category.

SPONSORS: Senators Wojahn, West, Sheldon and Sellar

SENATE COMMITTEE ON HEALTH & HUMAN SERVICES

Staff: Martin Lovinger (786-7443)

Hearing Dates: March 1, 1993

BACKGROUND:

The federal Food and Drug Administration (FDA) divides drugs into two classes: prescription and nonprescription (over-the-counter). Prescription drugs include habit-forming drugs and drugs which are not considered safe for use except under the direct supervision of a health care provider licensed to prescribe. Over-the-counter drugs are generally regarded as safe for consumers to use if they follow the directions and warnings on the required label. Over-the-counter drugs may be purchased without a prescription.

A number of drugs that were originally available by prescription only have been reclassified as over-the-counter. One problem with all drugs is the potential for serious harm from misuse. The potential for harm may increase, particularly in the area of adverse drug reactions, as the number of drugs available over-the-counter increases. Some believe that elderly consumers, who use more drugs, are more likely to suffer adverse drug reactions. The cost of dealing with adverse drug reactions can be expensive and is borne by the whole society through the health care system.

Pharmacists licensed in Washington are educated about the actions, indications, adverse reactions, and interactions of drugs. It is felt that creating a new category of drugs which would be available only from licensed pharmacists, but without prescription, would address some of the possible abuses of drugs that are reclassified from prescription status to over-the-counter. It is felt that drugs could be studied in this category until their safety for over-the-counter use is clearer and that an interim category could speed the process of moving drugs from prescription status to over-the-counter status.

SUMMARY:

The President and Congress are requested to authorize the Federal Drug Administration (FDA) to study a new transitional nonprescription drug category that designates drugs available for sale only through licensed pharmacists in order to evaluate for a specific period drugs being considered for over-the-counter release, with the goal to decrease the time needed for the FDA to approve a drug for over-the-counter status.

Appropriation: none

Revenue: none

Fiscal Note: none requested