SENATE HEALTH COMMITTEE

STATEMENT TO

SENATE COMMITTEE SUBSTITUTE FOR
SENATE, No. 1864

STATE OF NEW JERSEY

DATED: MARCH 20, 1997

The Senate Health Committee reports favorably a Senate Committee Substitute for Senate Bill No. 1864.

The purpose of this substitute is to protect the interests and safety of patients who are prescribed narrow therapeutic range (NTR) drugs.

Accordingly, this substitute exempts designated NTR drugs from mandatory substitution pursuant to the "Prescription Drug Price and Quality Stabilization Act," but allows substitution if the prescriber gives informed consent for the substitution. The substitute authorizes the Drug Utilization Review Council in the Department of Health and Senior Services to establish a list of NTR drugs using the criteria set forth in this substitute. The drug formulation shall have been approved by the federal Food and Drug Administration after 1938, shall meet the Food and Drug Administration criteria for narrow therapeutic ratio as provided in 21 C.F.R. 320.33 and shall meet at least three of the following criteria: that the narrow therapeutic range drug formulation is used to treat a critical acute or chronic condition; that the narrow therapeutic range drug formulation is associated with the risk of toxic reactions, complex drug-drug interactions or steep dose response curves; that the narrow therapeutic range drug formulation has highly individualized dosing requiring continuing dose supervision by the prescriber to ensure its safe use; or that there is a competent medical determination that a lack of bioequivalency could have a serious adverse effect in the treatment or prevention of a serious disease or medical condition. The council shall adopt the list pursuant to the "Administrative Procedure Act."

The substitute provides that a pharmaceutical manufacturer may apply to the council to have one of its drug formulations added to the list established by the council. Also, the substitute provides that the council shall make available, upon request, the complete list of NTR drug formulations designated by the council as subject to the provisions of the substitute.

The Drug Utilization Review Council also shall adopt, by regulation, a list of interchangeable drug products for the designated NTR drug formulations that shall be permitted for substitution by a pharmacist in the event that a prescriber gives informed consent for

substitution or the original prescription is written for the drug formulation's generic name.

In order to ensure that the most appropriate drug product is dispensed in the event that the pharmacist substitutes the drug formulation pursuant to the provisions of this substitute, the substitute provides that the selection of the interchangeable drug product shall be the responsibility of the pharmacist dispensing the product, and that no employer, agent or other person may require the dispensing of a particular drug product which in the professional judgment of the dispensing pharmacist is not in the best interest of the patient.

The provisions of this substitute apply to any pharmacist subject to the provisions of the "Prescription Drug Price and Quality Stabilization Act" and to a licensed inpatient health care facility with respect to a patient admitted to the facility who was being treated with a NTR drug at the time of admission.

The penalty for violating the provisions of the substitute is at least $100 for the first offense and $200 for each subsequent offense. These penalties are the same as those provided for any violation of the "Prescription Drug Price and Quality Stabilization Act."

NTR drugs are widely used for the treatment of a number of acute or chronic medical conditions, including heart attack, organ transplants, stroke, asthma, osteoporosis, epilepsy and depression. Drugs commonly considered to have a narrow therapeutic range include: carbamazepine, conjugated estrogens, digoxin, levothyroxine sodium, phenytoin sodium, cyclosporine, theophylline and warfarin sodium.

These drugs are designated as having a narrow therapeutic range because of the narrow margin that exists between patient benefit and patient risk. NTR drugs have highly individualized dosing, requiring close, careful and skilled patient monitoring to ensure that the level of the prescribed drug in the patient's blood stays within the narrow therapeutic range, or window, appropriate for that medication. A change in formulations of a NTR drug has the potential of causing the dosage to vary outside the therapeutic window, exposing the patient to the risks associated with too low or too high a dosage. Changes in formulation can include changing from a brand name formulation to a generic formulation or another brand name formulation, or from one generic formulation to another, or from a generic formulation to a brand name formulation.

This substitute will prohibit any change from the formulation upon which the patient was stabilized, to any other formulation, without the knowledge and consent of the prescriber of the drug.