Testimony re: HB 2538 House Health and Human Services Committee Presented by Debra L. Billingsley February 11, 2004

Mr. Chairman, Members of the Committee:

My name is Debra Billingsley, and I am the Executive Director of the Kansas Board of Pharmacy. The Board of Pharmacy consists of six members, five of who are licensed pharmacists, and one who is a representative of the general public. The Board's mission is that all persons and entities conducting business relating to the practice of pharmacy in this state be properly licensed and registered so as to protect the public's health, safety, and welfare and to promote the education and understanding of pharmacy related services.

HB 2538 establishes a drug repository program that would accept donations of prescription only drugs and dispense them to Kansas residents who meet certain eligibility requirements. The drugs may be donated by any person, drug manufacturer, or health care facility to a participating pharmacy, hospital or nonprofit clinic.

This bill has been authored with the best intentions and the Board's position is that any discourse that plans on providing safe and affordable health care to Kansans is worthy of discussion.

The Board supports the intentions behind the bill but would like to address some areas of concern.

The term prescription drug is defined in the Pharmacy Act and in federal law as any drug dispensed pursuant to a written or oral prescription or order of a practitioner. This would include controlled substances. Federal law, specifically 21 CFR 290.5, prohibits the transfer of a controlled substance to any person other than the patient for whom it was prescribed. Therefore, the language in the bill as written would violate federal law.

The Kansas Pharmacy Act also has a law that provides that prescription drugs that have been dispensed to the final consumer shall not be resold, re-dispensed, or re-distributed. The only exception is unit-dose systems with one medication where the drug hasn't reached the patient.

The reason that the federal law and state law prohibit members of the general public from returning their personal drugs, for distribution to others, are for safety reasons. This prevents any problems with tampering or storage. Many drugs are to be maintained at certain temperatures so these laws ensure that patients are receiving a safe and an effective product. We cannot ensure that the product is safe or effective when it reaches the hands of the consumer and then is put back into general stock for re-distribution.

Kansas's pharmacy law does permit patients who are receiving unit-dose systems the ability to return the medication for credit if it has not reached the patient. (See K.A.R. 68-12-2) This is particularly useful in the nursing home setting. If the drug does not reach the patient and his prescription changes or if the patient passes away the family may return the drug for credit.

This bill may duplicate some other efforts that are currently being made by drug companies. Manufacturers are currently donating pharmaceuticals to doctor's offices and They generally provide samples at no cost to the to charitable organizations. organization and they may only be given to the patient for free. Charitable clinics such as the Marian Clinic in Topeka are provided such samples and they give these to patients every day. There is also a Health Access program available in some Kansas counties. In this program a card is given to person that meets eligibility for assistance. The patient pays approximately \$4 for each prescription up to a maximum of \$740 a year. The Marian Clinic in Topeka is currently using this program. The Federal Government has the 340B Drug Discount Program that assists County Health Agencies and Charitable Organizations in providing low cost pharmaceuticals to eligible patients. I know that the Shawnee County Health Department has been exploring the use of this program although it is not currently in effect. Many of the chain pharmacies also have programs that assist low-income families with payment for pharmaceuticals if the patient applies for assistance. There is a program whereby physicians can apply for particular patients to receive complimentary drugs directly from the manufacturer. We would want to explore whether this bill will duplicate any of the efforts already available.

The bill has an expiration date of medication that can be used in this program of up to six months. Drugs in unit dose packaging have a one-year expiration date. The short date may eliminate some of the drugs that would otherwise be available for use.

The Board also wanted the Committee to reconsider any provision that would totally absolve persons donating from responsibility and liability. There is no accountability in this bill unless bad faith can be shown. Bad faith infers that an intentional act is done in order to achieve something. This would mean that if a licensee were professionally incompetent, negligent, or physically or mentally handicapped to such a degree that he would be unfit to practice, there might possibly be no legal liability. The Board is concerned that safety would be compromised absent an intentional act. We should apply the same safeguards for indigent patients as we apply toward any other patient.

The Board would request that the Committee review this bill more fully to make sure that the integrity issues are resolved. The Board of Pharmacy would be able to assist in any discussions or provide specific information if needed.

Thank you very much and I will be happy to answer any questions that you might have.