Approved: Mar. 20, 2007
Date

MINUTES OF THE HOUSE HEALTH AND HUMAN SERVICES COMMITTEE

The meeting was called to order by Chair Brenda Landwehr at 1:30 P.M. on February 14, 2007 in Room 526-S of the Capitol.

All members were present.

Committee staff present:
Norman Furse, Revisor's Office
Melissa Calderwood, Legislative Research
Mary Galligan, Legislative Research
Patti Magathan, Committee Assistant

Conferees appearing before the committee:
Senator Mike Peterson
Nancy Zogleman, Pfizer Corporation
Jack Geisser, Director of State Policy for Pharmaceutical Research Manufacturers of America
Debra Billingsley, KS State Board of Pharmacy
Julie Hein, National Association of Chain Drug Stores
Dan Bellingham, Health Care Distribution Management Association
Brian Caswell, Pharmacist
Donovan Pepper

Others Attending:
See Attached List.

Chair Landwehr opened the floor on hearings for **HB2392**- Registration requirements of pharmacy for wholesale distribution of drugs.

Senator Mike Peterson, Proponent, stated that this bill is important due to the rapidly growing problem of counterfeit drugs and the potential of a terrorist attack to our pharmaceutical supply. It is important to consumers to have confidence in the drugs prescribed to them as well as doctors having the confidence that medications are have their intended healing effect. More than two dozen states have enacted or are considering new and tougher documentation requirements of drugs being sold in their borders. (Attachment 1)

Nancy Zogleman, Pfizer Corporation, discussed, risks saying that this is a patient safety issue. This is the third year a similar bill has been introduced to the legislature. Ms. Zogleman showed a slide show which depicted counterfeit drugs alongside the real drugs, illustrating that there is little or no difference based on a physical comparison. This is a global problem that is escalating, with a 92% increase in counterfeit medications predicted from 2005 to 2010. **HB2392** is the work product of a study group made up of all interested parties and addresses the desire of the legislature to have recommendations for licensing and wholesale distribution legislation. (Attachment 2)

Jack Geisser, Director of State Policy for the Pharmaceutical Research and Manufacturers of America, said that his organization supports **HB2392**, however they would like to suggest amendments to comply with the Federal Prescription Drug Act regarding prohibited acts, definitions and licensing of wholesale distributors, electronic track and trace pedigree technology, reporting of suspicious/counterfeit activity and enforcement/penalties. (Attachment 3)

Brian Caswell, Pharmacist, Chairman of the Governmental Affairs Committee of the Kansas Pharmacists Association, and representative of the Kansas Pharmacy Coalition, stated that he is in opposition to **HB2392**. Pharmacists want a safe and legal means of delivering medications to their patients and support any means that helps to protect and safeguard against any threat to our nation's medication supply. **HB2392** may inadvertently create an environment that produces hurdles, slows down delivery to properly authorized and legal agents, and may actually fall far short of attaining its ultimate goal. The Kansas Pharmacists Association would like to recommend that the two key components of the bill be reexamined separately. Licensure of Wholesale distributors should be the first step in maintaining a safe and secure drug distribution system. The pedigree piece has many potential shortfalls and is reliant upon a futuristic model that has yet to be determined. (Attachment 4)

Opponent **Dan Bellingham**, Associate Director of State Government Affairs with Healthcare Distribution Management Association, fully supports stronger licensure requirements, increased criminal penalties, and effective and efficient pedigree requirements to secure the supply chain. He stated that, with all due respect, this 28-page bill should be addressed at the Board of Pharmacy. The language mirrors the N.A.B.P. Model Rules not the four page N.A.B.P. Model Bill. Those who were present at the November 2006 Board Stakeholders meeting agreed that the legislature should address a much shorter version, leaving the details to be worked out in rule making. Their concerns are 1.) Clarification that electronic pedigrees must start with the manufacturer. 2.) Language regarding "unknowingly" penalties language. 3.) More specifics on the use of third party accreditation programs. 4.) An explanation regarding the manufacturers exemption from stronger licensing requirements. (Attachment 5)

Opponent **Debra Billingsley**, Executive Director of the Kansas State Board of Pharmacy stated that the Board of Pharmacy has the responsibility for safeguarding the state's drug supply and regulating those involved in the distribution of medications. She informed the committee that the 2006 legislature mandated that the Board conduct a task forced to study the issue of counterfeit drugs, including pedigrees, penalty for violation of requirements, and registration requirements for wholesalers. The Board met on numerous occasions. Meetings were facilitated by an associate of the National Association of Boards of Pharmacy, with at least twenty different entities being represented at the meetings.

The Task Force determined that the first step in combating counterfeit drugs was to set high standards for registration of all distributors shipping into Kansas. They also agreed that penalties should be increased for those in violation of any provision of the Pharmacy Act. The Board of Pharmacy supports efforts to accomplish this goal.

The task force did not come to an agreement regarding the provision related to pedigree for the following reasons: 1.) No consensus on beginning point for pedigree being with the Manufacturer or with the Distributor, 2.) Availability of emerging technologies such as radio frequency identification is not commonly available, and paper pedigrees are of little value, 3.) The FDA has mandated pedigrees in the Prescription Drug Marketing Act, however there is pending litigation with the likelihood that the regulations are unconstitutional.

The Board of Pharmacy would submit that there needs to be more stringent requirements for registration of wholesale distributors, whether or not there is pedigree. We are providing a copy of bill language that would provide additional requirements and safeguards to the drug distribution channels. (Attachment 6)

Opponent **Julie Hein**, representing the National Association of Chain Drug Stores said that this is a technical issue and provided the written testimony of Kevin Nicholson, who is snowed in and unable to be here today. The Association provided an edited version of the bill that addresses several of their concerns (Attachment 7).

Mr. Donovan Pepper with Walgreens Corporation, provided some impromptu remarks. Wholesale pharmacy is not opposed to wholesale provisions and/or pedigree, and we are concerned about counterfeit drugs and adulterated products. There are provisions in this bill that need to be addressed. We hope that the Kansas legislature would consider federal legislation and legislation passed in other states when considering statute changes.

Chair Landwehr closed hearings on **HB 2392** and adjourned the meeting at 3:05 P.M. Next meeting will be February 15 at 1:30 P.M.