

Testimony Re: HB 2455
House Health and Human Services Committee
Presented by Ronald R. Hein
on behalf of Shire
January 21, 2015

Mr. Chairman, Members of the Committee:

My name is Ron Hein, and I am legislative counsel for Shire. Shire is a pharmaceutical company which, among numerous other drugs, manufactures Vyvanse, a drug used for treatment of ADHD and, more recently, moderate to severe Binge Eating Disorder in adults. This is the subject of the legislation being addressed today.

We requested introduction of HB 2455 and support it strongly. This bill was necessitated due to a statute enacted in Kansas in 1984. In 1984, the legislature enacted K.S.A. 65-2837 and K.S.A. 65-2837a. These statutes were adopted to address a problem with physicians prescribing drugs which had amphetamines as ingredients, and the legislature wanted to protect against physicians prescribing drugs which might be abused in the manner that methamphetamine was being abused. The statute made the prescription of such drugs by physicians a violation of the professional practice act, unless such drugs were specifically approved by K.S.A. 65-2837a. At the time this bill was enacted, Binge Eating Disorder was not even a recognized disease.

In January, 2015, the Food and Drug Administration approved Vyvanse, a drug developed by Shire, to be used for the treatment of moderate to severe Binge Eating Disorders in adults. Binge Eating Disorder is a disease which affects more people than anorexia and bulimia combined. Vyvanse had been approved for treatment of ADHD years previously, and treatment of moderate to severe Binge Eating Disorder beginning in January, 2015.

Vyvanse was able to be prescribed for treatment of moderate to severe binge eating disorder in adults in 45 states, but Kansas, and 4 other states, had statutes which prohibited the prescription by physicians for such purpose. K.S.A. 65-2837a needs to be amended to permit the medicine to be used for such purpose. K.S.A. 65-2837a also provides a mechanism whereby the Board of Healing Arts could approve the use of the drug if they determined that:

"The treatment of any other disorder or disease for which such drugs or compounds have been found to be safe and effective by competent scientific research which findings have been generally accepted by the scientific community, in which case, the licensee before prescribing, ordering, dispensing, administering, selling, supplying or giving the drug or compound for a particular

condition, or the licensee before authorizing a mid-level practitioner to prescribe the drug or compound for a particular condition, shall obtain a determination from the board of healing arts that the drug or compound can be used for that particular condition.”

On August 14, 2015, the Board of Healing Arts did approve a petition filed by a Johnson County psychiatrist seeking approval for the drug, and the approval of Vyvanse and its generic equivalent authorized physicians in Kansas to treat their adult patients with this medication for moderate to severe binge eating disorder. However, K.S.A. 65-2837a does not now recognize this specific treatment, so a physician reading only the statute, who does not know about the board of healing arts action, would think he or she could not prescribe this medication. In addition, the existing Board of Healing Arts could change their mind at any time, or a future Board of Healing Arts could reverse the decision and disallow such treatment.

So we believe it is extremely important to conform the statute to permit this drug to be prescribed by physicians, and to ensure that the patients of Kansas continue to be able to have this medical treatment available to them.

Throughout this past summer/fall, we have reached out to Kansas physician groups regarding this legislation. The following groups have indicated that they have no concerns or objections to this legislation: Kansas Medical Society, Kansas Association of Osteopathic Medicine, Kansas Academy of Family Physicians, and the Kansas Psychiatric Society, who will be testifying today as well. We have also reached out to the Mental Health Coalition, which is composed of numerous mental health groups and which has also indicated that they have no concerns or objections to this bill. Other physicians or groups have submitted statements or letters in support of this bill.

HB 2455 also updates the term “hyperkinesia” in subsection (b)(3).

We would simply request that this committee pass HB 2455 out of committee with a recommendation that it be passed.

Also appearing today on behalf of Shire is Ted Buckley, Director of Government Affairs for Shire, In addition, we have Barry Herman, Shire Medical Affairs Director of Neuroscience Strategy, and Susannah Henderson, Shire Legal Counsel, here to respond to any committee questions.

Thank you for permitting me to testify and I will be happy to yield to questions at any time.