Testimony Re: SB 465
Senate Public Health and Welfare Committee
Presented by Ted Buckley
Shire
Head of U.S. Government Relations and Public Affairs Team
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Mr. Chairman and Members of the Committee,

Thank you for giving me the opportunity to testify today. My name is Ted Buckley and I am here as a representative of Shire.

Who We Are & What We Do

As the Head of the U.S. Government Relations and Public Affairs Team, I am responsible for the development and execution of advocacy, education, and public healthcare policy on behalf of Shire in the United States. I joined Shire with 12 years of experience in public policy, public advocacy, and health economics after serving as the chief economist for Bloomberg Government and director of economic policy at the Biotechnology Industry Organization.

Shire manufactures and sells drugs and biologics in the neuroscience, gastrointestinal, and rare diseases spaces. Shire focuses on developing and delivering innovative medicines for patients with rare diseases and other specialty conditions. We are dedicated to improving the lives of those with rare diseases and other specialty conditions by developing and improving access to innovative treatments that meet their needs.

We are focused on access to medicines, disease awareness, and transparency. We have a responsibility to continually improve access to our therapies for patients around the world. I come to you because the current situation in Kansas has put our patients and their access to treatment at risk.

Patient Access to Treatments for BED in Kansas

I would like to build upon our legislative counsel, Ron Hein's testimony, and expound upon the necessity of SB 465, to ensure adult patients with moderate to severe BED have uninterrupted access to treatment and that physicians are never liable for prescribing within the bounds approved by the FDA. The first and only FDA approved treatment for adult patients with moderate to severe BED is Vyvanse.

Vyvanse is a central nervous system stimulant indicated for the treatment of ADHD in patients 6 years and older and Moderate to Severe Binge Eating Disorder in adults. Vyvanse was approved for the treatment of ADHD in 2007. In January of 2015, the FDA approved Vyvanse as the first drug in the United States to treat moderate to severe Binge Eating Disorder in adults. Vyvanse was reviewed under the FDA's priority review program, which provides for an expedited review of drugs that are intended to treat a serious disease or condition and may provide a significant improvement over the available therapy.

Since approval by the FDA, Shire's field team heard from several physicians that there may be some state rules in place that are preventing them from prescribing FDA-approved treatment options to their patients. Shire undertook a comprehensive review of all 50 states and determined that there are rules in five states, including yours, which could be interpreted as restricting prescribing of Vyvanse for anything other than ADHD.

It's important to understand that these state rules were not specifically designed to prevent access to Vyvanse for BED. These are simply outdated rules that have not been updated based on more recent advancements.

Successfully Clarifying Rules in Other States

In Ohio, Shire successfully obtained an amendment to State Medical Board regulations restricting prescriptions of sympathomimetic amine drugs such as Vyvanse to a limited number of conditions. The amended regulation makes clear that moderate to severe BED in adults is a condition for which prescriptions of Vyvanse is permitted. The amended regulation became effective on December 31, 2015.

In West Virginia, Shire was able to obtain written assurances from both the State Board of Medicine and Board of Osteopathic Medicine last September indicating that they would exercise their discretion and not commence disciplinary actions against physicians or osteopaths prescribing Vyvanse in a manner consistent with its FDA-approved labeling. In January 2016, a bill was filed to amend the state boards' regulations to include BED on the list of conditions for which Vyvanse may be prescribed. The bill has since been bundled with HB 4125 and has passed the House Health and Human Resources Committee. The bill is currently before the House Judiciary Committee awaiting to be bundled with the Senate miscellaneous rules.

In Washington, Shire has worked in parallel with the state's Pharmacy Quality Assurance Commission (PQAC) and the state legislature to address this issue. Both Houses of the state legislature have approved proposed legislation to amend the state's Controlled Substances Act to clarify that there is no limitation on a Washington physician's ability to prescribe Vyvanse for moderate to severe BED in adults. The bills are currently being reconciled. Further, last week PQAC voted in unanimous support to adopt proposed language to the Washington Administrative Code that would also facilitate Vyvanse prescriptions consistent with its FDA-approved indication to treat adults with moderate to severe BED.

In Tennessee, Shire has worked with the state legislature to propose a bill clearly protecting Tennessee HCPs who prescribe Vyvanse within its approved labeling and ensuring access to Vyvanse for adult patients with moderate to severe BED whose clinicians prescribe the drug. Bill in both the House of Representatives and Senate to protect Tennessee HCPs who prescribe Vyvanse within its approved labeling were filed. Legislation has passed the Tennessee Senate and will be heard this week in the Tennessee House Health Committee.

We are working diligently with policymakers, allies, and patient organizations to change and clarify the rules to ensure access to Vyvanse as a treatment option for adult patients with moderate to severe BED. We believe that guaranteeing access to this FDA-approved treatment option is the right thing to do.

Thank you for your consideration. I would be happy to answer any further questions.