

Via e-mail and Regular US Mail

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Re: Adderall XR® Consumer Advertisements

Dear Mr. Lacasse and Dr. Leo:

Thank you for your letters, the first dated August 1, 2005, and the second postmarked September 19, 2005, in which you brought to our attention your concerns arising from two direct-to-consumer advertisements for Adderall XR, Shire's product for the treatment of Attention-Deficit/Hyperactivity Disorder (ADHD). The two ads carry the internal Shire codes AJ44 June 2005 and AJ72 August 2005.

In your August letter, you question whether Adderall XR "can be accurately advertised as a 'solution' for ADD". As you are aware, the DSM-IV-TR® recognizes inattention, impulsivity, and hyperactivity as the core impairments of ADHD. These symptoms are more frequent and severe than would be expected in those of similar age and development, and must be seen in two or more settings, such as home and school. In clinical trials involving children, Adderall XR has been shown to reduce these core symptoms to a range comparable to those children without ADHD.ⁱ Adderall XR has been evaluated for safety and efficacy in more than 20 clinical studies of children, adolescents, or adults. In addition, the statement that Adderall XR is a trusted solution for this behavioral condition is supported by the fact that more than 200,000 doctors have prescribed Adderall XR for their patients diagnosed with ADHD. Since 1996, more than 40 million prescriptions have been written for Adderall or Adderall XR.ⁱⁱ

We do not claim that Adderall XR is "the" solution to ADHD. In Shire patient education materials available to both patient and physician, we recommend that ADHD medication be included as part of an overall treatment plan that may include behavioral therapy, academic counseling, and life-skills coaching. The treatment regimen appropriate for a particular patient would be part of the prescribing decision that occurs in the office setting between patient and physician.

You also questioned the statement in the advertisement, "schoolwork that matches his intelligence" and whether Adderall XR has been shown in scientific research to result in sustained improvement in global academic performance. In clinical studies employing an analogue


classroom setting, study subjects treated with Adderall XR were evaluated across a 12-hour day using the PERMP (Permanent Product Measures of Performance), a clinical evaluation tool employing a math productivity test to compare medication against placebo. In these trials, patients treated with Adderall XR had sustained, clinically significant improvements in academic productivity, including the number of math problems attempted and number answered correctly.ⁱⁱⁱ

Additionally, you challenge the statement "Friends that ask him to join the group". Many physicians have recognized that the inattentive, impulsive, and hyperactive symptoms experienced by children diagnosed with ADHD may result in poor relationships with their peers, who may see such behavior as disruptive or distracting to team or group activities. As demonstrated in clinical trials, Adderall XR has been shown to improve these core symptoms of ADHD to that of their non-ADHD peers, which may ease the negative stigma associated with this condition.

Finally, in your September letter, you suggest that the testimonial of Ty Pennington is not reflective of the experience of others who may be prescribed Adderall XR. As you will note in this and the June advertisement, it is noted that Adderall XR may not be right for everyone and patients considering treatment are advised to speak with their physician before and during treatment.

Thank you for your concerns and for giving us an opportunity to address them.

Sincerely,



Julio Casoy, M.D.
Senior Vice President
Global Medical Affairs

ⁱ Biederman J, Lopez FA, Boellner SW, Chandler MC. A randomized, double-blind, placebo-controlled parallel-group study of SLI381 (Adderall XR) in children with attention-deficit/hyperactivity disorder. *Pediatrics*. 2002; 110:258-266.

ⁱⁱ IMS National Prescription Audit (NPA), 1996-2004.

ⁱⁱⁱ McCracken JT, Biederman J, Greenhill LL, et al. Analogue classroom assessment of a once-daily mixed amphetamine formulation, SLI381 (ADDERALL XR), in children with ADHD. *J Am Acad Child Adolesc Psychiatry*. 2003; 42:673-683.