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Thomas Abrams, R.Ph, MBA
Office of Medical Policy
Director, Division of Drug Marketing, Advertising, and Communications
Food and Drug Administration
5600 Fishers Lane, HFD-42
Rockville, Maryland 20857
Phone: (301) 827-2831
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Dear Mr. Abrams:

We are writing to alert you regarding a recent direct-to-consumer advertisement which we believe warrants further investigation from your office.

In the August 22, 2005 issue of *People* magazine, we find a direct-to-consumer advertisement for Amphetamine-Dextroamphetamine (Adderall) which makes advertising claims which seem to be odds with the prescribing information and peer-reviewed scientific literature (advertisement enclosed for your convenience).

We previously wrote another letter to the FDA regarding a direct-to-consumer advertisement for Adderall by Shire. The current advertisement is slightly modified in terms of visual content, but includes similar and/or identical advertising claims. We are concerned that there is the potential for a sustained advertising campaign which includes objectionable content, but which is not addressed by the FDA.

We ask that you please consider this matter as soon as possible, since millions of consumers are being exposed to these ads, and we believe that many consumers will assume they are accurate because they are regulated by the FDA.

We are concerned regarding the following statements found within this advertisement:

1. Ty Pennington’s testimonial.

The current advertisement invites readers to a website, adderallxr.com/ty, which contains a celebrity testimonial by Ty Pennington. Under “Ty’s Story”, this website states that Adderall XR does not negatively affect Mr. Pennington’s eating or sleeping patterns. However, the prescribing information for Adderall reports a 33% rate of loss of appetite, 11% rate of weight loss, and a 27% rate of insomnia among adults prescribed Adderall in clinical trials. We are concerned that consumers reading this website may believe that Mr. Pennington’s experience with Adderall was typical, and that they may underestimate the importance or prevalence of adverse reactions due to this advertising. We note that the FDA has, in the past, issued warning letters to manufacturers for disseminating overly positive testimonials which omitted risk information.

2. “A Trusted Solution for ADHD.”

We question whether Adderall can be accurately advertised as a “solution” for ADD. Certainly many children diagnosed with ADHD receive prescriptions for psychostimulants. However, every textbook on ADHD also addresses psychosocial interventions as well, such as behavioral treatment, educational interventions, family therapy, and so on. Current ‘evidence-based practice’ recommends using psychostimulant medications as one treatment modality among many in the integrative, combined treatment of ADHD. This is noted in the Adderall prescribing information. If Adderall alone is a solution for ADHD, why are psychosocial approaches recommended in addition to medication?

It is also clear that children diagnosed with ADHD, even when receiving treatment with psychostimulants, often retain some of the behaviors that initially led to their diagnosis (e.g., they may still exhibit behaviors that are labeled as hyperactive or impulsive). Therefore, we are not aware of any psychiatric research which has established that Adderall will actually “solve” ADHD.

Is the phrase “A trusted solution for ADHD” an exaggerated advertising claim, or is there evidence supporting this claim which we are unaware of?

3. “Schoolwork That Matches His Intelligence.”

We question the veracity of this statement. We are unaware of any scientific research which demonstrates that the administration of Adderall will result in a sustained improvement in global academic performance. We have not seen any psychiatric research which establishes, for instance, that children on Adderall will manifest academic performance more highly correlated with their IQ than children who are administered a placebo. We suspect that such experiments have yet to be conducted.

We are aware that some short-term studies have demonstrated that the administration of Adderall is correlated with improvement on a 10-minute math test. We question whether this testing is equivalent to “schoolwork”, which, to us, means global academic performance, including many other subjects unrelated to mathematics. It seems to us that report cards and grade point average are the most important measures of “schoolwork” in our society. We have not seen any research demonstrating that Adderall improves long-term academic performance, as measured by grades.

Therefore, we wonder whether the phrase, “Schoolwork that matches his intelligence” is an accurate reflection of an improvement on a 10-minute math test. Or, is this perhaps a misleading claim? We could find no data in the prescribing information and would welcome clarification.

4. “Friends That Ask Him To Join The Group.”

We are unaware of any peer-reviewed scientific literature that could be cited to support this statement. The prescribing information for Adderall only includes information on the effects of Amphetamine-Dextroamphetamine on individuals. No information is provided regarding predictable effects on the social contacts of those individuals who take Adderall.

Parents of children who have been labeled as ADHD probably desire that their children be socially well-adjusted, for good reasons. However, has it been scientifically demonstrated that children who are administered Adderall have reliably improved relationships with their peers as a direct result? Or, is this desired outcome being promoted as a predictable response, without supporting data?

We are concerned about this point because Adderall is known to cause nervousness, emotional lability, and social withdrawal. Obviously, these symptoms could be harmful to social adjustment. As you know, the FDA is currently investigating the relationship between psychostimulants and psychotic symptoms, aggression, and suicide. Thus, it seems that Adderall is being marketed using the statement, “Friends that ask him to join the group”, when, in fact, Adderall appears to have the potential to cause psychiatric symptoms which are destructive to the process of social adjustment. We would appreciate an explanation of the discordance between the advertising claim and the data.

We are hopeful that we have pointed out some important issues that your agency can address. Based on the content we have presented here, we hope you will strongly consider issuing a warning letter to Shire.

In any case, we know the FDA carries a heavy regulatory burden, and appreciate your time and consideration in taking the time to read our letter.

We respectfully request that you apprise us of the status of our complaint by sending postal mail to Jeffrey Lacasse at the address listed above.

Sincerely,

Jeffrey R. Lacasse, MSW, Ph.D. Candidate
Florida State University

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