



GlaxoSmithKline

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Dear Healthcare Professional:

Recently the FDA posted a Talk Paper to their website referring to the use of *Paxil* for pediatric depression. This communication acknowledged that the FDA is reviewing reports a possible increased risk of suicidal thinking or suicide attempts with *Paxil* vs placebo in children and adolescents with depression. Although the FDA did recommend that *Paxil* not be used for treating pediatric depression, many of the media reports inaccurately indicated that this was a final decision by the FDA on the safety of *Paxil* in children and adolescents. The Talk Paper is not a final decision from the FDA on their evaluation of the safety data of *Paxil* in children and adolescents with depression.

GSK will continue to work with the FDA in analyzing and reviewing the data with paroxetine in children and adolescents. Although we cannot provide specific information regarding the data currently under review, upon completion of the review and agreement on the data by the FDA and GSK, we will communicate with you to provide you the appropriate clinical information regarding *Paxil* and use in children and adolescents with depression. If a decision is made to discontinue *Paxil*, it is important that *Paxil* not be discontinued abruptly.

It is important to note that in clinical studies of more than 1000 children and adolescents not a single patient committed suicide. Furthermore, with respect to adults, the FDA stated that "[e]xtensive analyses of the data from studies with *Paxil* in adults and from post marketing adverse event reports have not revealed an increase in the rate of suicidal thoughts or suicide attempts compared to placebo."

We want to assure you that we continue to stand firmly behind *Paxil* as a safe and effective medication that continues to help millions suffering from mood and anxiety disorders.

After more than ten years of real-life experience and clinical trials in thousands of patients, *Paxil* is one of the most studied and analyzed medicines. The overwhelming body of data shows no link between *Paxil* and suicide, suicidal thinking or suicide attempts.

If you have any questions about *Paxil*, please contact our Medical Information Department at 1-888-825-5249.

Sincerely,

Philip D. Perera M.D.
Group Director, Psychiatry
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