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October 25, 2007

Andrew C. von Eschenbach, M.D.
Commissioner
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857-0001

Dear Dr. von Eschenbach:

I am writing to express my significant concern regarding the Food and Drug Administration's revised antidepressant medication guides, entitled "Antidepressant Medicines, Depression and other Serious Mental Illnesses, and Suicidal Thoughts or Actions." The previously used medication guides included specific guidance and warnings to parents of young children who are prescribed antidepressant drugs; the new medication guides dilute the clarity and power of those warnings, and as such deny parents information vital to the safety of their children.

As you know, for several years I have been focused on ensuring parents are aware – through black box warnings and medication guides – of potential adverse side effects in children who are prescribed antidepressant medications. In 2005 and 2006, my office conducted an examination of whether medication guides for antidepressant prescriptions were actually reaching parents. We contacted several pharmaceutical manufacturers, pharmacist trade associations and state boards of pharmacy. That examination resulted in important changes in public policy, including state boards of pharmacy inspecting pharmacists' compliance with medication guide distribution.

In recent years, as stakeholders have commented on the content included in antidepressant medication guides, there has been one constant and shared goal – disseminating as much pertinent information to patients as possible. When it comes to adolescent patients, it is clear to me that the FDA's new antidepressant medication guide fails to meet this basic goal and actually is a profound step backward. Moreover, the revision does not reflect the FDA's Public Health Advisory on October 15, 2004, announcing that the agency was developing a "multi-pronged strategy" to warn the public about the increased risk of suicidal thoughts and behavior in children being treated with antidepressants.

The new antidepressant medication guides are universally written for all patients regardless of their age; they replace antidepressant medication guides specifically written for parents of children. The previous version was descriptive of the side effects and

warning signs most commonly seen in adolescents using antidepressant medication. The revised version, however, abbreviates much of that information and combines numerous age pools into a generic warning.

For example, in the previous medication guide, this information was both clear and direct:

“What is the most important information I should know if my child is being prescribed an antidepressant?”

“Parents or guardians need to think about 4 important things when their child is prescribed an antidepressant:

“1. There is a risk of suicidal thoughts or actions...”

and

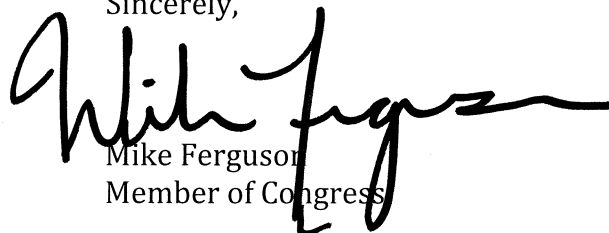
“Children and teenagers sometimes think about suicide, and many report trying to kill themselves. Antidepressants increase suicidal thoughts and actions in some children and teenagers.”

That clear, straightforward language has been replaced. Moreover, while the previous medication guides maintained a principal focus on children and the potential for adverse reactions among children, the new medication guides delete this singular focus by combining “children, teenagers and young adults.”

Your staff told my office that the new antidepressant medication guides were developed to ensure each age population was aware of the risks associated with antidepressant medications. I applaud the effort to ensure every patient is fully informed. But I believe in trying to achieve that laudable goal, the new medication guides mitigate information about the risks and potential adverse reactions among younger patients.

While studies submitted to your agency show that older patients do face risks or potential adverse reactions when taking antidepressant medications, those studies also demonstrate younger patients face those risks and potential adverse reactions at a higher frequency. That alone, in my judgment, warrants a stand-alone warning to parents, as the previous medication guides offered.

Sincerely,

A handwritten signature in black ink, appearing to read "Mike Ferguson". The signature is fluid and cursive, with a long horizontal stroke at the end.

Mike Ferguson
Member of Congress