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of the Disease of Obesity*

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December 8, 2004

Dr. Lester Crawford
Acting Commissioner
Food and Drug Administration
Room 14-71
Parklawn Bldg.
5600 Fishers Lane
Rockville, MD 20857

RE: Senate Testimony of Dr. David J. Graham on sibutramine

Dear Dr. Crawford:

As you know, on November 18, 2004, Dr. David J. Graham, Associate Director for Science, Office of Drug Safety, Center for Drug Evaluation and Research, testified before the Senate Committee on Finance regarding the Food and Drug Administration and Vioxx.

During the course of this testimony, Dr. Graham was asked by Senator Jeff Bingaman about other drugs of concern. Dr. Graham responded stating that there were five drugs he thought "should be looked at." One was sibutramine (Meridia). Dr. Graham stated:

And I think it needs to be carefully looked at because it only works if you take it for a long time, but nobody stays on it for more than a month, just about, because they can't tolerate the side effects. So they get the side effects – they get the risk of raised blood pressure and stroke, and they don't stay on it long enough to lose weight that it's (sic) going to make a difference. So to me, a question like, sort of, what's the utility of that drug? And actually, we had done a study two years ago in which we point this out, and our management made us take that conclusion out of it. We were forced to take out of it: This observation raises the utility of the continued marketing of this drug. That got taken out of the report. So sibutramine is one.

As you know, the American Obesity Association is an educational and advocacy organization supported by lay persons, professionals and corporate members of whom Abbott Laboratories is one. The American Obesity Association (AOA) is very concerned about Dr. Graham's comments for the following reasons.

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1. Unlike other therapeutic areas, there are only 2 FDA approved drugs for the treatment of obesity and Meridia is one.
2. Meridia has been studied in over 100 clinical trials involving over 12,000 patients. Approximately 15 million persons have taken Meridia in 75 countries.
3. Dr. Graham's statement "nobody stays on it for more than a month" appears to contradict other information on patient utilization which average 3 to 6 months.
4. Dr. Graham states that patients "can't tolerate its side effects". Yet the data on withdrawal rate for Meridia indicates it is about the same as placebo. The most common adverse events are headache, dry mouth, anorexia, constipation and insomnia which are common side effects to many pharmaceuticals, are usually of short term duration and easily resolved.
5. Dr. Graham also states the reason for discontinuation of the drug is "they get the risk of raised blood pressure and stroke." This doesn't seem logical. Surely most patients know of the risks of Meridia before taking it. Why would they go off a drug for a risk they knew was there when they started? Blood pressure increase is a well-known effect in some patients taking Meridia and it is easily monitored.

We are aware that the FDA has issued a general statement that the five drugs mentioned by Dr. Graham in his testimony are considered safe and effective. However, we very strongly feel that this is insufficient to correct the damage done by Dr. Graham's testimony. We feel his statements are highly likely to confuse both physicians and patients on Meridia's safety and efficacy.

Dr. Graham also mentioned a study he conducted whose conclusions were repressed by the FDA. We are interested in knowing if this study was part of the petition filed by Public Citizen in March 2002 on Meridia. This petition has languished at the FDA ever since and has left a cloud of doubt about Meridia which Dr. Graham has exacerbated.

The American Obesity Association believes that it is time for the Food and Drug Administration to rule on this petition and make a definitive statement about the safety and efficacy of Meridia.. Thank you for your attention.

Sincerely,

Morgan Downey
Executive Director