**Pediatric Drug Labeling Update**

**Statsin, diet and exercise can help lower cholesterol in some cases**

From the AAP Priority Drugs and Pediatric Labeling Education Project Advisory Committee

This is another in a series of AAP News articles that highlights the results of pharmaceutical clinical trials, allowing pediatricians to practice rational therapeutics.

The drug described below, atorvastatin, is one of many with new labeling based on pediatric studies. New legislation has allowed the Food and Drug Administration (FDA) to offer incentives (exclusivity) to companies that perform pediatric studies. The cumulative list of drugs granted exclusivity with labeling changes that resulted from pediatric exclusivity studies is available on the FDA Web site at www.fda.gov/cder/pediatrics/labelchange.htm. This site highlights the changes made to the labels only from exclusivity. The label may have been updated recently for other reasons. The Drugs@FDA Web site at www.accessdata.fda.gov/scripts/cder/drugsatfdal/index.cfm gives electronic access to the most recent label changes.

When Tommy’s cholesterol rose, Dr. Karma suspected an interaction with St. John’s wort, which Tommy began using to self-treat depression after breaking up with his girlfriend.

When Tommy’s health maintenance organization changed its formulary, Dr. Karma could prescribe similar drugs, simvastatin or lovastatin, because they, too, had been studied in children.

After making the same diagnosis in Tommy’s 8-year-old brother, Dr. Karma confidently prescribed pravastatin, proven safe and effective in children this young.

Disseminating information about new drug labeling is an objective of the AAP/FDA contract, Priority Drugs and Pediatric Labeling Education Project. The AAP Committee on Drugs (COD) is the Project Advisory Committee (PAC) for this initiative. Members of the COD and PAC developed all vignettes. For more information about this project, contact Sheryl Nelson at snelson@aap.org or (800) 433-9016, ext. 7103.

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