

AAP News, the official newsmagazine of the American Academy of Pediatrics, is dedicated to informing, educating and inspiring readers on matters related to pediatric health care.

EDITOR IN CHIEF

Anne Hegland

ASSOCIATE EDITOR

Trisha Koriath

SENIOR WRITER/EDITOR

Carla Kemp

STAFF WRITER

Alyson Sulaski Wyckoff

WASHINGTON CORRESPONDENT

Taryn Houghton Rosenkranz

EDITORIAL INTERNS

Kari Bachmeier

Rachna Sheth

ART DIRECTOR

Michael Hayes

PRE-PRESS PRODUCTION SPECIALIST

Mark A. Krajcecki

EDITORIAL ADVISORY BOARD

Mika Hiramatsu, M.D., FAAP, Chair
Castro Valley, Calif.

William L. Coleman, M.D., FAAP
Chapel Hill, N.C.

Laura Ferguson, M.D., FAAP
Houston, Texas

Barbara Frankowski, M.D., FAAP
Burlington, Vt.

Gilbert L. Fuld, M.D., FAAP
Keene, N.H.

Daniel Levy, M.D., FAAP
Owings Mills, Md.

Kathleen Nelson, M.D., FAAP
Birmingham, Ala.

Peter Rogers, M.D., FAAP
Columbus, Ohio

AAP NEWS PUBLISHER:

American Academy of Pediatrics

President

Carden Johnston, M.D., FAAP

Executive Director

Errol R. Alden, M.D., FAAP

Associate Executive Director

Roger F. Suchyta, M.D., FAAP

Department of Education Director

Robert Perelman, M.D., FAAP

Division of Medical Journals and

Professional Periodicals Director

Nancy Deal Chandler

AAP NEWS ADVERTISING POLICY

Publication of an advertisement in AAP News neither constitutes nor implies a guarantee or endorsement by AAP News or the American Academy of Pediatrics of the product or service advertised or of the claims made for the product or service by the advertiser.

AAP NEWS ADVERTISING REPRESENTATIVE:

The Walchli Tauber Group, Inc.

(443) 512-8899

Gary Walchli: ext. 102

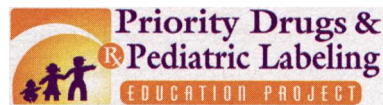
Steve Tauber: ext. 103



PEDIATRIC DRUG LABELING UPDATE

Statins, 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/pediatric/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/drugsatfda/index.cfm gives electronic access to the most recent label changes.

The Jones family walked through the doors of Heartland Pediatrics after having breakfast at a fast-food restaurant. New patients, they filled out the usual paperwork, including their personal and family health histories.

Dr. Karma, Heartland's junior associate, read the histories and became concerned. Tommy's grandparents had died before age 50 from heart attacks. Nobody in the family exercised. Everybody ate a diet high in salt, sugar and fat. Tommy had no history or symptoms of liver, kidney or endocrine disease nor did he take medications. However, his body mass index was 29, and his blood pressure was 145/90 mmHg.

Dr. Karma prescribed the National Cholesterol Education Program Step One diet, counseled Tommy regarding exercise and arranged for laboratory tests. Results showed Tommy's total cholesterol was 310 milligrams per deciliter (mg/dL) and his low-density lipoprotein (LDL) cholesterol was 240 mg/dL. Dr. Karma diagnosed heterozygous familial hypercholesterolemia.

Tommy complied with his diet and started to work out. He lost weight and his blood pressure normalized, but his cholesterol remained very high: total was 250 mg/dL and LDL-C was 190 mg/dL. The Step Two diet made no difference, and Tommy started to rebel. After consulting the AAP Web site (www.aap.org), Dr. Karma decided to begin drug therapy.

He prescribed atorvastatin, an HMG-CoA reductase inhibitor recently labeled for use in children 10 to 17 years of age with Tommy's disease. Studies mandated by the FDA told Dr. Karma to start with a dose of 10 mg daily, information readily available on the Internet (www.fda.gov/cder/pediatric/labelchange.htm). With diet and exercise, Tommy's cholesterol measurements fell to a total of less than 200 mg/dL and LDL-C to less than 130 mg/dL; increasing the dose to 20 mg daily normalized these values.

Routine tests excluded hepatotoxicity. Dr. Karma stopped atorvastatin when Tommy complained of muscle pain; creatine phosphokinase measurement was normal, pain was attributed to exercise, not rhabdomyolysis, and the drug was safely restarted.

When Tommy developed sinusitis symptoms, Dr. Karma avoided erythromycin, knowing the antibiotic may increase atorvastatin blood levels and cause serious muscle injury; symptoms, too, may have been a minor side effect.

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 ssnelson@aap.org or (800) 433-9016, ext. 7103.

ANNOUNCEMENT

2005 CERTIFYING EXAMINATIONS OF THE AMERICAN BOARD OF PEDIATRICS

111 SILVER CEDAR COURT • CHAPEL HILL, N.C. 27514-1513

Telephone: (919) 929-0461 • Facsimile: (919) 918-7114 or (919) 929-9255

Web site: www.abp.org

First-time applicants using training to qualify for most certifying examinations may complete applications online during the registration periods for new applicants. **The final month of each registration requires payment of a late fee.** The requirements for online applications may be found on the ABP Web site: www.abp.org or may be obtained by contacting the ABP. Additional information including eligibility requirements and registration dates may also be found on the ABP Web site.

GENERAL PEDIATRICS

EXAMINATIONS:

Examination Date:

Oct. 31 and Nov. 1, 2005.

Registration for first-time

applicants: Dec. 1, 2004

through May 2, 2005.

Registration for

re-registrants: Feb. 15, 2005 through May 31, 2005.

SUBSPECIALTY

EXAMINATIONS:

Neurodevelopmental Disabilities (online registration is not available for this examination)

Examination Dates:

April 4-8, 2005.

Registration for first-time

applicants: July 1, 2004,

through Sept. 30, 2004.

Registration for re-registrants:

Sept. 1, 2004, through

Dec. 1, 2004.

Sports Medicine

Examination Dates: To be

determined by ABFP.

Registration for first-time

applicants: Sept. 15, 2004,

through Dec. 15, 2004.

Registration for re-registrants:

Dec. 16, 2004, through

March 15, 2005.

Pediatric Endocrinology -

Examination Date:

Aug. 18, 2005

Pediatric Gastroenterology -

Examination Date:

Aug. 17, 2005

Pediatric Infectious Diseases -

Examination Date:

Aug. 19, 2005

Registration for first-time

applicants: Sept. 15, 2004,

through Dec. 15, 2004.

Registration for re-registrants:

Dec. 16, 2004, through

March 15, 2005.

Adolescent Medicine -

Examination Date:

Dec. 1, 2004

Pediatric Nephrology -

Examination Date:

Nov. 29, 2005

Neonatal-Perinatal Medicine-

Examination Date:

Nov. 30, 2005

Registration for first-time

applicants: Feb. 1, 2005,

through May 2, 2005.

Registration for re-registrants:

March 15, 2004, through

June 16, 2005.