

POLICY & PRACTICE

Approving Follow-On Biologics

Creating a regulatory pathway for approving generic or "follow-on" versions of biologic therapies would improve competition and curb rising biotech prices, according to an analysis from the Competitive Enterprise Institute. Congress is considering legislation that would allow an abbreviated approval process for so-called follow-on biologics. This pathway would be similar to the process currently in place for approving generic pharmaceuticals. Whether this regulatory pathway is created through legislation or out of the Food and Drug Administration's existing authority, the report maintains that the process could be done safely. Generic manufacturers have the capability to create safe follow-on biologics, and the FDA has the tools to recognize products that are comparable with existing drugs or interchangeable, wrote study author Gregory Conko, a senior fellow at the Competitive Enterprise Institute. "Consumers would see tremendous benefits from an abbreviated approval process for generic biotech prescription drugs," Mr. Conko said in a statement. "In addition to the cost savings, the competition that these approvals would generate could spur even more improvements in the quality of biopharma-

ceuticals." Find the report online at www.cei.org/gencon/025,05933.cfm.

Lupus Grants Awarded

The Department of Defense's Congressionally Directed Medical Research Program awarded over \$2 million in the form of two grants for research on lupus and lupus biomarkers. The grants will fund investigations in mouse models, but the findings could lead to human advances. Researchers at the Medical University of South Carolina in Charleston will experiment with targeting a certain cascade of proteins in a mouse model to target certain areas where lupus causes tissue damage and to minimize immune suppression in other areas of the body. Grant recipients at the Feinstein Institute for Medical Research at the North Shore Medical Center in Manhasset, N.Y., will examine the estrogen's role in triggering lupus activity in certain mouse models but not in others. That research could have long-term implications for testing patients with lupus for hormonal disorders.

AMA Fights Medicare Cuts

Physicians report they will severely limit the numbers of Medicare patients they treat if Congress won't avert planned

Medicare physician payment cuts, which will total 10% on Jan. 1, 2008, and will reach about 40% over the next 9 years, according to an American Medical Association survey of nearly 9,000 physicians. If Medicare payment rates are cut by 10% in January, 60% of physicians report they will limit new Medicare patients and 40% will limit established Medicare patients, the AMA survey found. "As physicians brace for 9 years of steep payment cuts, it will be extremely difficult for them to continue accepting new Medicare patients," said Dr. Cecil Wilson, AMA board chair. "The baby boomers begin entering the program in 2010, and the Medicare cuts increase the likelihood that there may not be enough doctors to care for the huge influx." MedPAC, Congress' advisory committee on Medicare, has recommended Congress halt next year's 10% cut and update payments 1.7% in line with practice cost increases.

State Variations in Care Cost, Quality

Cost, quality, and access to care vary widely depending on where you live, according to a report from the Commonwealth Fund. The report ranks states based on 32 indicators of access, quality, avoidable hospital use and costs, equity, and healthy lives. While no state ranked first across all indicators, in general states in the North-

east and Upper Midwest performed better, while southern states tended to score the lowest. "The differences we found between the top and bottom states were shocking, often a two- to threefold variation or greater," study coauthor Cathy Schoen said in a statement. "Where you live clearly matters for access to care when you need it, the quality of care you receive, and opportunities to live healthier lives."

New FDA Risk Panel

Following an Institute of Medicine recommendation, the FDA has created an advisory committee charged with helping the agency communicate the risks and benefits of pharmaceuticals and other products. In 2006, the IOM's report, *The Future of Drug Safety: Promoting and Protecting the Health of the Public*, urged Congress to establish a new advisory panel that would weigh in on the FDA's communications about safety and efficacy to health care providers and the public. The agency found an administrative process that let it establish the committee without congressional action. The FDA is now seeking 15 members to serve on the Risk Communication Advisory Committee, including experts on risk communication, social marketing, health literacy, journalism, bioethics, and cultural competency.

—Mary Ellen Schneider

CLASSIFIEDS

Also Available at www.rheumatologynews.com



MDA

Muscular
Dystrophy Association
Jerry Lewis, National Chairman
1-800-572-1717
www.mdausa.org

Disclaimer

RHEUMATOLOGY NEWS assumes the statements made in classified advertisements are accurate, but cannot investigate the statements and assumes no responsibility or liability concerning their content. The Publisher reserves the right to decline, withdraw, or edit advertisements. Every effort will be made to avoid mistakes, but responsibility cannot be accepted for clerical or printer errors.

PROFESSIONAL OPPORTUNITIES

Lahey Clinic Rheumatologist

Outstanding opportunity available for a BC/BE Rheumatologist to join our department consisting of six physicians and two Nurse Practitioners. Opportunity for academic appointment to Tufts Medical School, teaching Lahey residents and fellows and students from Tufts Medical School. Our multi-disciplinary group practice model allows close collaboration within the medicine center, providing patient care that covers a wide spectrum of rheumatology conditions, and offering participation in selected opportunities for clinical trials research with a dedicated research assistant.

Lahey Clinic is conveniently located in Burlington, a scenic suburb 30 miles northwest of Boston, and a short drive to the adjoining New England states. This multi-disciplinary group practice with a 317-bed hospital, state-of-the-art facilities and outpatient clinic treats more than 1 million people per year. As part of Lahey Clinic's continuing growth, we are expanding Lahey Clinic North Shore in Peabody, MA, and offer a referral network through our community group practices across eastern Massachusetts.

We offer competitive salaries and compensation, plus a comprehensive benefits package. **To apply, please forward a letter of interest and CV to Lahey Clinic, Attn: Kathryn Schnabel, Physician Recruitment Office, 31 Mall Road, Burlington, MA 01805; Email: Kathryn.A.Schnabel@lahey.org.** EOE



Lahey
CLINIC

www.lahey.org

TREATING YOU RIGHT.™

BEST READERSHIP, LOW COST QUALIFIED LEADS

2007

CLASSIFIEDS

Rheumatology News Rates

4 Column Classified Ads

From 1" to 12"

Ads starting at \$135

For Deadlines and More Information Contact: Eric Kun
Tel: 212-633-3746 or fax your ad to 212-633-3820
Email ad to: e.kun@elsevier.com



Rheumatology News

Elsevier-Rheumatology News
360 Park Avenue South
New York, NY 10010