Policy & Practice

NIH Lupus Research Plan

Government scientists recently outlined plans for future lupus research. The goals include laying the foundation for lupus prevention, identifying disease triggers, defining target organ damage mechanisms, understanding autoantibodies, discovering and validating biomarkers, and advancing therapy. These goals are part of a long-range planning document recently released by the National Institute of Arthritis and Musculoskeletal and Skin Diseases, of the National Institutes of Health. The NIH document predicts lupus prevention could become an "attainable goal" in the next decade. Mandated by Congress, the plan was developed with input from lupus experts, according to NIH. "The ultimate goal of this plan is to identify needs and opportunities from both public and private organizations to continue to accelerate progress in lupus research to further improve quality of life of patients who have lupus," Dr. Stephen Katz, director of NIAMS, wrote in the plan's introduction.

Vioxx Class Action Suit Denied

A ruling that gave nationwide class-action status to insurance companies seeking reimbursement for rofecoxib (Vioxx) expenditures was overturned Sept. 6 by the New Jersey Supreme Court. The Court agreed with Merck, maker of rofecoxib, that the claims of the insurance companies and HMOs were different and therefore not appropriate for a class action suit; however, the court did rule that plaintiffs may pursue individual suits against the company. "Although we respectfully disagree with the Court's conclusion, we are pleased that our client's substantive claims are preserved. Importantly, the Court's ruling gives us the green light to pursue these claims," said Christopher A. Seeger, lead lawyer for the plaintiffs, said in a statement.

Grant Awarded in Oklahoma

The National Institutes of Health has awarded $2.66 million to the Oklahoma Medical Research Foundation to establish the Oklahoma Rheumatic Disease Research Cores Center. The center's first pilot projects will evaluate a new molecule to determine whether it is a candidate future lupus therapies and examine risk factors for autoimmune disease in children. The money also will support junior researchers as well as researchers from outside of rheumatology, said Dr. Judith James, the principal investigator on the grant, who holds the Lou C. Kerr Chair in Biomedical Research at OMRF.

WHI Results Still Confusing to MDs

Just 18% of physicians said they have "no confusion at all" about the results of the Women's Health Initiative study, according to an online survey of more than 400 physicians conducted on behalf of The Hormone Foundation. In addition, only 15% believe patients accurately understand the risks of hormone therapy. The results "underscore the importance of physicians' role in educating patients and [the public] on menopause management," said foundation director Paula Correa. The survey, sponsored by Novogyne Pharmaceuticals, also found that 74% of physicians still consider hormone therapy first-line treatment for menopause symptoms. Novogyne manufactures the hormone therapy patches, Vivelle-Dot, Vivelle, and CombiPatch.

FDA Wins Reauthorization

The Food and Drug Administration Amendments Act of 2007 passed Congress and was signed into law by President Bush just days before its slated expiration date of Sept. 30. The Act contained within it provisions to collect "user fees" from pharmaceutical and medical device makers to review their products, monitor direct-to-consumer advertising, and track recalls of medical devices, among other things. The "user fees" fund 25% of the agency's operating budget, said FDA Commissioner Andrew C. von Eschenbach in a statement. The agency also was given authority to require drug and device makers to disclose clinical trial data publicly and to fine manufacturers who do not do so in a timely manner, and more power to order postmarketing clinical trials. Notably absent from the final version of the bill was the creation of a regulatory pathway to approve generic versions of complex biologic agents (see related story, p. 1).

Insurance Premium Increase Slows

Employer-sponsored health insurance premiums rose on average 6.1% in 2007, reflecting a continuing slowdown in premium increases. The 2007 increase is the smallest since 1999, according to a survey by the Kaiser Family Foundation and the Health Research and Educational Trust. But experts say the slowdown is temporary and isn't providing relief to individuals or employers. The 6.1% increase is higher than the average wage increase (3.7%) and the overall inflation rate (2.6%). In 2007, the average premium for family coverage in the U.S. is $12,106. Workers pay about $3,281. Preferred provider organizations insure about 57% of covered workers; consumer-driven plans account for about 5%. For details, visit www.kff.org/insurance/7672.

—Denise Napoli

Biologic Patents Set to Expire

Generics *from page 1*

nology. "Because biologics are extracted from living systems, elements from culture media or purification processes may remain in the final therapeutic mixture," altering its safety and efficacy profile.

That means generic biologics may have to undergo the same expensive, lengthy clinical trials to which their branded versions were subjected.

Dr. David Fox, director of the rheumatic disease core center at the University of Michigan, Ann Arbor, said the cost of biologics can influence his management of severe rheumatoid arthritis. "When I prescribe a biologic, I am thinking about whether this patient has coverage for medications. If they don't, I think hard about other alternatives that might be almost as good or maybe equally good."

However, even if legislation enabling a biogeneric pathway had passed, it would take years before rheumatologists had the opportunity to prescribe them, said Dr. Fox, who also is president-elect of the American College of Rheumatology.

And even then, "For me, the level of comfort [with prescribing biogenerics] is going to depend on whether the FDA has had the opportunity to go through a sufficient process of scientific evaluation to establish that a follow-on biologic is similarly safe and effective as the original."

The ACR's official position on the issue states: "While cost savings are highly desirable, the approval process for generic biologics needs to place safety and efficacy, supported by scientifically sound evidence, as the highest priorities."

The fact that any regulatory pathway for biogenerics may include clinical trials has led some to question whether they could indeed confer savings proportional to those of small-molecule generics.

Consultant David E. Williams said in an interview "Biosimilars are a bad idea all around. They. . . are complicated to develop and regulate, and aren't likely to bring down prices very much [because of these limitations]. A better idea is to regulate the prices of biotech drugs once their patents expire," said Mr. Williams, cofounder of MedPharma Partners LLC, a consultancy in Boston. Mr. Williams disclosed no conflicts of interest.

Data from at least one mathematical analysis at Duke University, Durham, N.C., has borne this out. "If the pharmaceutical market size is $1 billion, then we expect that on average, 12 generic pharmaceutical manufacturers would enter by the end of the first year of generic competition," wrote Henry G. Grabowski, Ph.D., director of the program in pharmaceutical and health economics at Duke, and associates (Managerial and Decision Economics 2007;28:439-51).

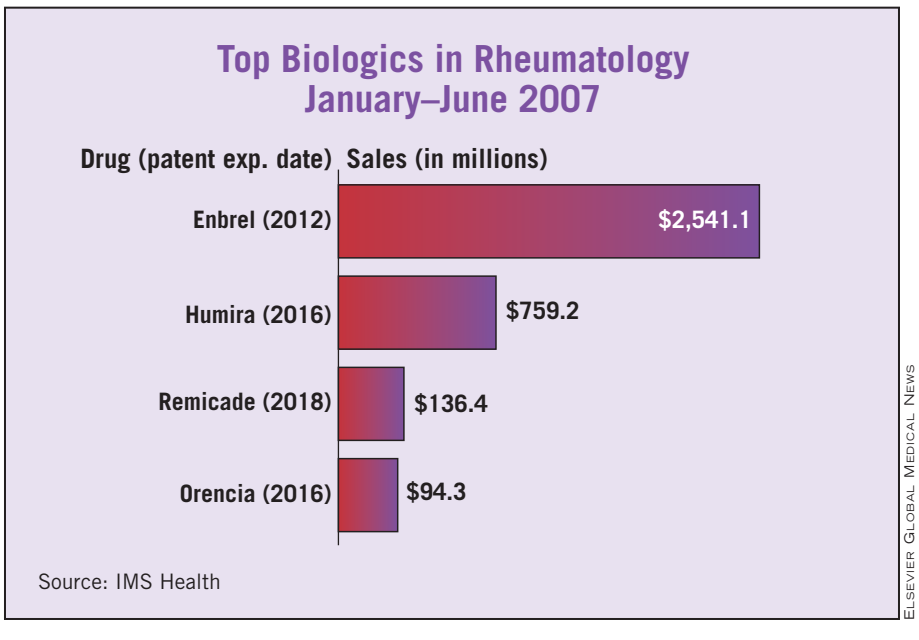
If fixed costs to manufacture and market a biogeneric agent were 100% higher than the researchers estimated, their model predicted six generic firms would enter. If the costs were 150% higher—what the researchers still consider a conservative estimate—just three generic firms would enter.

The researchers then determined "if there are 12 generic manufacturers, then generic prices are expected to be only 33% of branded prices." With three manufacturers, generic prices would be 75% of the branded price. "For the case of one generic entrant, which could prevail in many large biologic markets for a lengthy period of time, generic prices would be 90% of the branded price, given the estimates in our model," they wrote.

The study was funded by Genentech, which manufactures Rituxan.

The prescription drug user fee act (PDUFA), from which the biogenerics bill was cut, authorizes the FDA to collect application fees from drug companies, and was set to expire Sept. 30. These fees are crucial to the FDA's operating budget; not passing the bill would have meant layoffs.

Although earlier versions of PDUFA contained placeholders for biogeneric legislation, PDUFA's must-pass nature meant a compromise could not be reached in time. ■



Index of Advertisers