BY GARY SULLIVAN

High Hopes, High Costs

When research produces expensive therapies, what can be done to end injustices in access?

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One of the most anguished health-care concerns voiced by people with MS is the high cost of prescription drugs. New drugs arrive on the market, hope soars, and then many people who need the therapy discover the cost is prohibitive.

This phenomenon isn't restricted to people with MS—but expense of new drugs for other conditions can be relieved in time by the appearance of more affordable "generic" versions. A generic drug is one that contains exactly the same active ingredient(s) at the same strength as the brand-name drug. But there is no generic competition for most of the MS disease-modifying therapies. (See why not in the box on page 60.)

Access to affordable prescription drugs

A recent Society-sponsored survey of 983 people with MS in the United States found that 96.3% had some form of health insurance—a notably

higher percentage than the general population. Still some 70% of all surveyed said they had at least some difficulty paying for health care, including 30% who said they delayed or postponed seeking care because of cost. Nearly a third of the 70% reporting difficulties said that they spent less on food, heat, and other necessities to meet their health-care needs.

Lead investigator Lisa I. Iezzoni, MD, who has MS herself, collaborated with researchers and experts at Harvard Medical School, University of Massachusetts, Boston, and the National MS Society. The results were published on January 29, 2007, in an early online release of the journal **Multiple Sclerosis**.

The Society also conducted an informal survey on use of the Medicare Part D prescription drug plan among people living with MS. At least 10% reported that they had stopped taking their disease-modifying therapy for financial reasons. As one respondent noted, "I reached the Medicare donut hole … and it was just too much."

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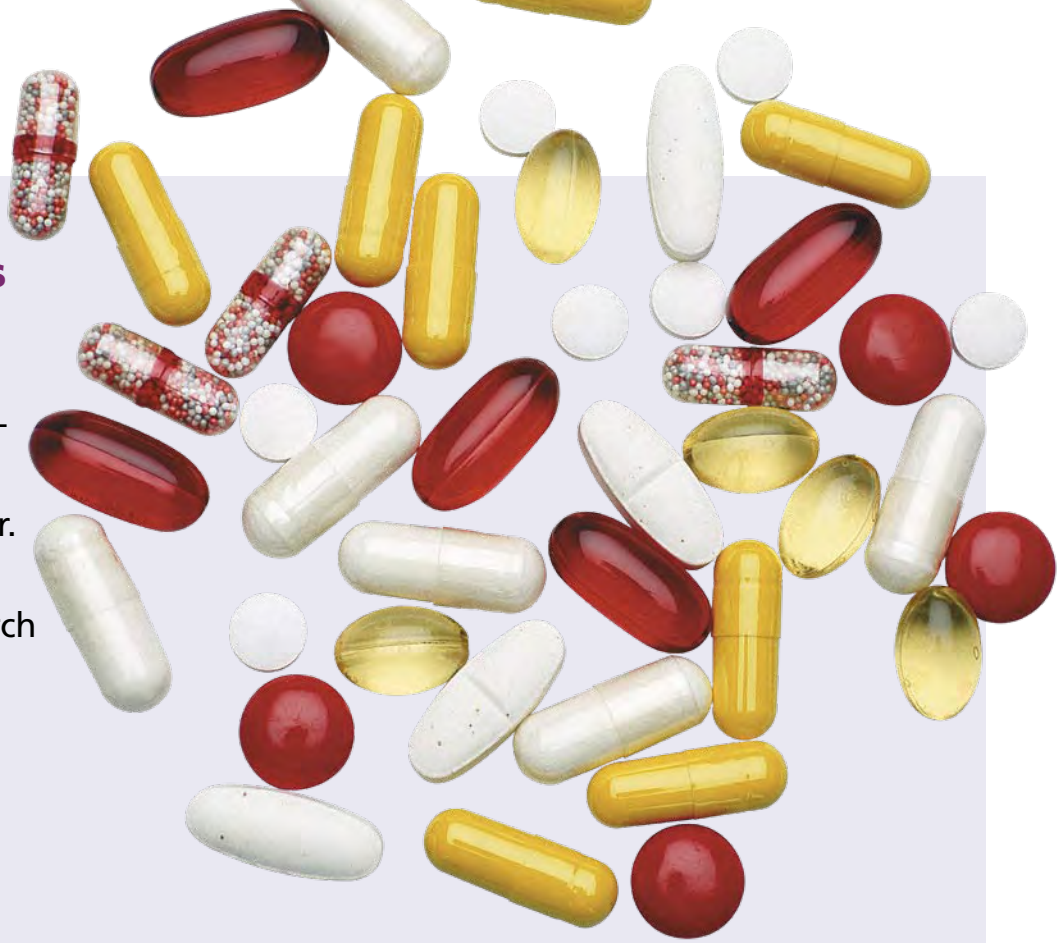
"We need to address the issue on a number of levels," David Chatel, the Society's new executive vice president of Advocacy, told **InsideMS**. Chatel was previously director of patient advocacy for the Centers for Medicare and Medicaid Services. "We'll be focusing on Medicare prescription drug coverage and how to navigate the coverage gap, insurance barriers including higher co-pays for higher-priced drugs (also known as "tiers"), the pricing of biological drugs by the pharmaceutical industry, and the potential for generic substitutes," Chatel said.

Cost-effectiveness study could lead to access

A study funded by the National MS Society and launched by Dr. Katia Noyes at the University of Rochester, New York, is investigating the relative cost-effectiveness of Avonex, Betaseron, Rebif, and Copaxone.

"Depending on the results of Dr. Noyes' study, we may get data that will encourage policy-makers to ensure that these drugs are accessible to all who need them," said Dr. Nicholas LaRocca, associate vice president of Health Care Delivery and Policy Research at the Society. The three-year U.S. study will be completed in July 2008.



Why most MS disease-modifiers have no generics

"Most of these MS treatments are what we call 'biologics,'" explained Dr. John Richert, executive vice president for Research and Clinical Programs at the Society. "They were developed using genetic engineering technology and are grown in living bacteria or mammalian cells." They are more difficult and expensive to produce than most other kinds of drugs. Because of the way they're produced, there can be variability in the end product when another manufacturer tries to reproduce it. We need to make sure that any generic versions actually have the same efficacy and safety as the brand-name drugs," Dr. Richert said.

The FDA does not currently have a standard process for approving generic versions of biologic drugs, called "follow-on biologics," but new legislation could remedy that. There's yet another wrinkle: "It's uncertain how much testing the FDA is going to require before allowing a generic biologic on the market," Dr. Richert pointed out. Additional testing could drive up the cost, but may be necessary.

Moving toward a change

Last March, under Chatel's leadership, more than 350 MS activists trooped to Capitol Hill and asked their legislators to support the Access to Life-Saving Medicine Act. This federal legislation would allow the FDA to approve applications for generic versions of biotech drugs, or "follow-on biologics," including disease-modifiers, and potentially give people living with MS some more affordable options.

Think globally ... act locally

Several Society chapters have been advocating to keep or add MS disease-

modifiers to private health insurance formularies, or lists of covered drugs, offered in their states. The Rhode Island Chapter scored a win. Their activists got MS injectable drugs included in the formulary for the Rhode Island State Pharmaceutical Assistance for the Elderly. This program is available to seniors 65 and older, and to people with disabilities 55 and older, who do not have prescription drug coverage and who are ineligible for Medicaid.

Across the country the fight for more equitable access to prescription drugs continues in neighborhoods, in state houses, and in the halls of Congress. Something **can** be done. Find out what's happening in your state by calling **1-800-344-4867**.

New standards for the bottom line

"Cost-effectiveness studies analyze quality of life as it relates to health and looks at what costs are involved in improving health-related quality of life," Dr. Nicholas LaRocca, associate vice president of the Society's Health Care Delivery and Policy Research Program explained. "Research on health-related quality of life began in earnest with the study of people with cancer." Cancer treatments were extending people's lives but the quality of the life for many was quite poor—partly due to the impact of the disease and partly due to the major side effects of the treatments. This led investigators to develop the concept of "quality-adjusted life years," a way of combining quantity and quality.

"For a person in perfect health, one year of life would equal one quality-adjusted life year," Dr. LaRocca said. "But if someone has a medical condition that impacts quality of life, one year of life might be considered equal to less than one quality-adjusted life year."

Today cost-effectiveness studies often look at how much it would cost to improve the health of a person to the point where quality-adjusted life years are close to actual life years. This is a scientist's way of saying that a cost-effective treatment enables people to move ahead with their lives. Dr. LaRocca pointed to a British cost-effectiveness study led by Jim Chilcott and published in the March 8, 2003, issue of the **British Medical Journal**. The quality-adjusted life-year data contributed to the successful effort to get MS disease-modifying drugs accepted by the British National Health Service.

"A cost-effective treatment enables people to move ahead with their lives."

Join the movement

For regular updates on legislative and regulatory issues like quality health care and prescription drug access, sign up for MS activism newsletters. Visit national mssociety.org/Advocacy. ■

Gary Sullivan is managing editor of this magazine.