

'Breathe Better' campaign garners attention for COPD

By AMANDA BALTAZAR

BETHESDA, Md. — Despite being cited as the fourth killer in the United States by the National Institutes of Health (behind heart disease, cancer and stroke) and likely to be in third place by 2020, chronic obstructive pulmonary disease is under-diagnosed by the medical profession and barely known by consumers.

Some 24 million Americans have COPD, an umbrella term for emphysema and bronchitis, diseases that inflame airways and trap bad air in the lungs, according to the National Institutes of Health's National Heart, Lung and Blood Institute. Around half of these people are unaware of it.

The death rate for COPD sufferers has exploded by 163 per-

cent in the last 30 years. The NHLBI launched a campaign earlier this year to increase awareness and encourage people ages 45 and older—especially those who have smoked—to get a simple breathing test and talk to their physician if they have symptoms of COPD.

These symptoms can include shortness of breath, wheezing, chronic coughing and fatigue, and usually are caused by smoking.

Because few Americans have heard of COPD, they may dismiss these symptoms or assume they have asthma. There's no cure for COPD but treatment is available, most commonly in the form of GlaxoSmithKline's Advair/Seretide, which saw sales of more than \$3 billion in 2006 in the world's major pharmaceutical markets (United

States, France, Germany, Italy, Spain, United Kingdom and Japan) and Boehringer Ingelheim/Pfizer's Spiriva (tiotropium bromide), a once-a-day inhaled medication that had annual global sales of approximately \$1.9 billion in 2006.

A report from Decision Resources estimates that the COPD drug market will nearly double from \$5.8 billion last year to \$10.6 billion by 2016.

"The increased uptake of premium-priced current and emerging COPD maintenance therapies such as GlaxoSmithKline's Advair/Seretide, Boehringer Ingelheim/Pfizer's Spiriva, GlaxoSmithKline/ Theravance's Beyond Advair combination agent and Novartis' indacaterol/glycopyrronium will be driven by growing acceptance of these drugs," said

Regina Cebula, analyst at Decision Resources.

Reports say that around half of COPD sufferers die within 10 years of their initial diagnosis, so the first step needs to be awareness.

The NHLBI's Learn More Breathe Better campaign aims to lessen the death rate. Radio and print media public service announcements are garnering attention and community organizations can download materials including an educational video, fact sheets and a reference card from the campaign's Web site or order them in bulk.

The campaign also is sending a 12-foot trailer emblazoned with its logo around the country offering free spirometry examinations that test lung function and provides COPD information at health fairs and other venues.

Another campaign, run by the American College of Chest Physicians is targeting primary care physicians and internists to increase their knowledge of this disease and test for it as routinely as they do other, better-known, diseases.

Once diagnosed, the most important thing a patient can do is stop smoking. But they also need to take medication, frequently a combination of Advair and Spiriva, to alleviate their symptoms.

The availability of these drugs doesn't mean patients will take them and according to a report by Frost & Sullivan, "U.S. COPD Market: Therapeutic Overview and Patient Outlook," COPD is cited as having the fourth-highest rate of non-compliance—and it estimates that prescription compliance is less than 50 percent.

Industry

CONTINUED FROM PAGE 17

increase dispensing fees to pharmacies to mitigate the impact of the likely drug reimbursement cut.

"Still, we think many states won't increase the fees until the second half of 2008 or 2009," they added.

Overall, Weinswig and Heldman concurred with

industry predictions that "Medicaid generic drug payments to pharmacies would drop on average ... 17 percent under the current proposal to begin reimbursing using average manufacturer price as the metric for payment."

In a June 25 conference call hosted by Citibank on the change in Medicaid drug reimbursement policy and its impact on retail pharmacies, John Coster, vice president of

policies and programs for the National Association of Chain Drug Stores, agreed that the states could help offset the impact of the fee reductions by increasing their own dispensing fees. Coster also noted that the delay was good news for pharmacies, because it spares them from Medicaid cuts at least until 2008 and gives them more time to lobby the states to help fill in the payment gap.

In the meantime, the retail pharmacy lobby has been active. Both NACDS and the National Community Pharmacists Association seized on a study released in June by the Department of Health and Human Services' Office of Inspector General.

Based on market data and policy plans in effect in the second quarter of 2006, the study analyzed the expected impact of the new AMP-based pricing regulations on retail pharmacy. In its report, the OIG acknowledged that the shift in payments for Medicaid prescriptions could significantly erode pharmacy margins and hamper the ability of some pharmacies—particularly those that serve high populations of low-income patients covered by Medicaid—to continue serving those patients.

Federal inspectors concluded that many drugs would cost pharmacies more to obtain than they what they could recoup from Medicaid.

"As intended by the DRA of 2005, federal upper limit amounts are likely to decrease under the new calculation method," noted the HHS inspector general's report. "We estimate that federal upper limit amounts will decrease by a median of 61 percent under the new calculation method set forth in the DRA."

The report goes on to estimate that FULs for 492 of the 521 drugs under review—94 percent—would be reduced under the new DRA requirements, "with 334 [64 percent] decreasing by at least half." It adds, "Federal upper limit amounts for 90 of the 521 drugs would be at least 90 percent below the second-quarter 2006 amounts."

The OIG found that the average pharmacy acquisition costs for 19 of 25 selected high-cost drugs "would have been higher" than what the federal program would have reimbursed them—and more than double in some cases.

In response, both NACDS and NCPA issued calls for immediate action in Congress to fix the Medicaid prescription payment regulations with new legislation.

"This report confirms the serious concerns raised by community pharmacy, the Government Accountability Office, other inspector general reports, and the 250 members of Congress who have gone on record in letters to CMS or the Depart-

ment of Health and Human Services," said NACDS president and chief executive officer Steve Anderson.

"The OIG report adds to the overwhelming evidence that Medicaid cuts are threatening consumer access to medications and pharmacy services as a result of the Medicaid pharmacy reimbursement formula," added NCPA executive vice president and chief executive officer Bruce Roberts.

One federal health official sought to tamp down the controversy, noting that the OIG report was merely "a snapshot of what would have happened if the new statutory formula was applied in [second-quarter] 2006, without taking into consideration changes that would result in 2007 that will impact AMP and thus, the final numbers." In its report, however, the OIG recommended that when it sets new upper limits, CMS "should take steps to identify when a new federal upper limit amount may not be representative of a drug's acquisition cost to pharmacies." The report also urged CMS to give pharmacies the opportunity to alert the states and CMS when they can demonstrate they are not able to purchase a drug at or below the new FUL amount.

Anderson said NACDS "will launch an effort to ensure Congress is aware of the findings of the report."