Medicare Part D: Big Dollars and Little Sense?

Politicians may have touted the new government-subsidized prescriptions offered to Medicare enrollees as cost-efficient, but before the launch of Medicare Part D many clinicians braced for the worst. They expected confusion over the options and sign-up process, so they did what they could to educate patients on how to make the best choice. They expected questions, so they learned about the "doughnut hole" between regular and catastrophic coverage. But few patients—and perhaps only the most pessimistic physicians—expected to see the prices for prescriptions increase sharply under the new plans. According to two recent studies, this is exactly the situation.

Families USA, a nonprofit non-partisan organization, examined the Medicare Part D prices for the top 20 drugs prescribed for seniors from mid-November 2005 to mid-April 2006. The group found that the median price for these medications increased by 3.7 percent over this period. Of particular interest to neurologists:

- 100 percent of the Part D plans raised their prices for simvastatin (Zocor)
- 97 percent raised their prices for atorvastatin (Lipitor)
- 94 percent raised their prices for celecoxib (Celebrex)
- 92 percent raised their prices for donepezil HCl (Aricept)
- 89 percent raised their prices for clopidogrel (Plavix)

The study also compared the prices of these drugs in Part D plans to Veterans Administration plans and found that, for all 20 drugs studied, VA prices were lower.

Another study by the AARP found very similar results in the overall prices of drugs pre- and post-Part D. This well-known advocacy group followed the wholesale prices for brand name and generic treatments for the 12-month period that ended on March 31. The AARP found the price of brand-name treatments rose 3.9 percent in the first quarter of this year, almost four times the rate of inflation during that period, with the price of zoldipem tartrate (Ambien) rising 13.3 percent.

The Pharmaceutical Research and Manufacturers of America has issued rebuttals to both studies. It asserts that the Families USA study is based on discredited information and that drug prices for Medicare beneficiaries are lower than expected, and that it was unfair to compare Medicare plans to the VA drug system. It also disputes the AARP's findings by citing data from a variety of government agencies to show that drug prices are in line with inflation and the rate of increase is actually slowing down. **PN**

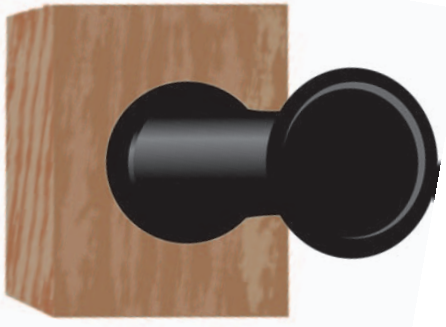
SHORTTAKES

■ **Injecting Relief.** A new study adds to the growing body of evidence that supports the efficacy of botulinum toxin type A (Botox) as a prophylactic migraine treatment. A randomized and double-blind study conducted by Frederick G. Freitag, DO, Associate Director of the Diamond Headache Clinic in Chicago, followed 36 chronic migraine patients who had discontinued or limited the use of their pain medication over a four-week period and received either 100 units of Botox or placebo injections. The findings, which were revealed at the 48th Annual Meeting of the American Headache Society in Los Angeles, showed that the treated arm experienced 26.9 percent fewer days with migraine per month compared to a six percent increase in the placebo group.

■ **Opening the Window Wider.** A small study may give hope for those who find the three-hour window for tPA administration too limiting for acute stroke care. A trial conducted at the Cleveland Clinic in Ohio studied the effectiveness of desmoteplase in 37 patients who had perfusion and diffusion mismatch on MRI from three to nine hours after the episode. They were randomized at 90mcg/kg, 125 mcg/kg, or placebo. MRI confirmed reperfusion in 53.5 percent of the higher-dose desmoteplase patients, 18.2 percent of the lower dose group and 37.5 percent of the placebo, and there were no cases of symptomatic intracranial hemorrhage detected. The researchers concluded that the treatment appeared safe at a higher dose, but the results would need to be confirmed in a larger randomized trial. *(Stroke 2006;37:1227-1231)*

■ **Good Night and Good Morning.** A common complaint associated with sleep medications is the lingering next-day residual effects, including psychomotor and memory effects. However, ramelteon (Rozerem) may help insomnia patients get to sleep at night without making them drowsy the next day. Data from a double-blind, randomized study, which was presented at the SLEEP 2006 20th Anniversary Meeting of the Associated Professional Sleep Societies in Salt Lake City showed that those taking this medication in either 8mg or 16mg doses experienced a significant decrease in time to fall asleep and, according to a variety of tests, did not experience next-morning residual effects.

FDA Gives OK to Two New Parkinson's Drugs



Movement disorders specialists and their patients have cause to both cheer and sigh: the good news is that they now have two more treatments at their disposal to treat the symptoms of Parkinson's disease; the bad news is that a once-promising prospect has been pulled from the pipeline.

On June 15th Valeant Pharmaceuticals announced it has received FDA approval for selegiline (Zelapar) as an adjunctive treatment with levodopa and carbidopa. In clinical studies Zelapar reduced the "off" time experienced by PD patients by 2.2 hours per day compared to 0.6 hours for placebo. The company received an "approvable" letter for this treatment back in October 2005, but the FDA requested more data before making its decision.

The FDA approved Novartis's formulation of rivastigmine tartrate (Exelon) for mild-to-moderate dementia in Parkinson's patients, the first drug approved for this indication, on June 27th. In a 24-week trial of 541 patients, Exelon was associated with higher scores on various mental scales than placebo. This treatment was approved for Alzheimer's patients with mild to moderate dementia in 2000.

However, German pharmaceutical manufacturer Merck announced it will not file for approval and not pursue further development for its compound sarizotan. This treatment was intended to treat dyskinesia in Parkinson's patients, but the phase III trials failed to confirm the results from phase II trials or preclinical research. The results from the double-blind, placebo controlled studies (PADDY-1 and PADDY-2) will be presented at the Movement Disorder Society's 10th International Congress of Parkinson's Disease and Movement Disorders in Kyoto, which runs from October 28 to November 2. **PN**

SHORTTAKES

■ **MOH Better Blues.** Medication overuse headache has been a common problem for years, and changing the predominant rescue medication hasn't helped to eliminate it. A review of patient charts from one acute center looked at the causes of MOH in 1200 patients during 2005, 2000, 1995 and 1990, with 300 patients evaluated at each interval. The number of patients with a probable MOH diagnosis remained remarkably stable but the medication changed, with probable ergotamine overuse headache falling from 18.6 percent in 1990 to zero percent in 2005 while the use of triptans rose from zero percent to 21.6 percent. The frequency of overuse headache from simple analgesics rose from eight to 31.8 percent, and for combinations of acute medications from 9.8 percent to 22.7 percent. *(Headache 2006;46:766-772)*

■ **Kicking RLS.** Three studies presented at the SLEEP 2006 20th Anniversary Meeting of the Associated Professional Sleep Societies in Salt Lake City indicated that a popular Parkinson's treatment can help RLS patients keep still at night. The first, a multi-center, randomized, double-blind, placebo-controlled parallel group study, showed that patients treated with pramipexole experienced reduced RLS symptom severity during sleep at all levels. Another study showed that withdrawal from a previously successful treatment with pramipexole led to a prompt worsening of RLS symptoms and the reoccurrence of sleep disturbances. A third placebo-controlled study showed that individually optimized doses of pramipexole taken two to three hours before bedtime did not produce daytime sleepiness for RLS patients and, in fact, significantly reduced sleepiness compared to placebo.

■ **Beyond the Pain.** The effects of chronic pain often take a devastating toll on the lives of patients, and a survey from the American Pain Foundation helped show some of the deeper effects. The Voices of Chronic Pain patient survey, which included 303 chronic pain suffers who take opioids, found that as a result of the pain more the 77 percent reported feeling depressed, 70 percent said they had trouble concentrating, and 52 percent said their chronic pain has put a strain on their relationships with family and friends. In addition, 70 percent said their pain has a great deal of impact on their work and 50 percent have lost a job due to chronic pain.

■ **The Vaccine Dream.** A study reported in PNAS *(2006;103;9619-9624)* may raise the hopes of those hoping to see a vaccine for Alzheimer's. Researchers at the Tokyo Metropolitan Institute for Neurscience announced a DNA-based vaccine proved effective in preventing beta-amyloid producting in murine models, reducing the levels of buildup by 50 percent after a year compared to controls.