Washington Week: FDA Issues Menthol Warning

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Review

WASHINGTON -- It was a slow week on Capitol Hill but elsewhere advisory groups were grinding out advice as Medicare advisers said doctors should get a small pay bump for 2012 and FDA advisers slammed big tobacco for adding menthol to cigarettes.

MedPAC Report Calls for 1% Pay Hike for Docs

The Medicare Payment Advisory Commission (MedPAC) officially recommended that physician reimbursement under the Medicare program be increased by 1% in 2012.

In its report to Congress last year, MedPAC also recommended a 1% pay increase, justifying the size by explaining that most Medicare patients have access to physicians and there doesn't appear to be any doctor shortage.

In addition, they noted, contrary to threats that doctors will stop accepting new Medicare patients, the vast majority of physicians are not shutting their doors.

The MedPAC trustees also recommended a 1% payment update to hospitals that treat Medicare patients, which is better news for hospitals than last year's report, in which MedPAC recommended a 2% reduction in each of the next three years to make up for over payments made in 2008 and 2009. The over payments were the result of changes in the use of new diagnosis-related groups in 2008.

Congress should pass legislation that allows the government to recoup those over payments, the trustees wrote.

If reimbursement goes up for doctors and hospitals, it has to go down someplace else. The MedPAC trustees singled out long-term care for that honor as they recommended cuts in home healthcare services, and no payment increase for skilled nursing facilities, in-patient rehabilitation facilities, long-term care hospitals.

Report Highlights Menthol's Harms

Removing menthol from cigarettes would improve public health, according to a report from the FDA's Tobacco Products Scientific Advisory Committee (TPSAC).

The panel released its recommendations on Friday, concluding that it is "biologically plausible" that adding menthol to cigarettes makes them more addictive and harder to quit and that companies that sell menthol cigarettes target minorities and kids with

their advertising.

Although the report came down hard on the practice of adding menthol to cigarettes, it stopped short of recommending that the FDA order cigarette companies to stop selling menthol products.

About 19 million people in the U.S. smoke menthol cigarettes, which accounts for between 28% and 34% of all U.S. smokers. Overall, three in 10 adult smokers use menthol cigarettes.

Adolescents 12 to 17 years smoke menthol cigarettes at a higher rate than any other age group, according to the TPSAC report. About half of middle school smokers and 45% of high school smokers said they usually smoke a menthol brand.

The panel said there is sufficient evidence to conclude that menthol cigarettes are marketed disproportionately to younger smokers and to African Americans.

The report will now be reviewed by experts at the FDA Center for Tobacco Products. The FDA has no deadline by when it must act, but will provide a progress report on its review in 90 days.

The FDA is not required to follow the advice of its advisory committees, but in the case of drugs and medical devices, it often does follow panel recommendations.

Panel Endorses Brain Devices

The Neurological Devices Advisory Committee voted 7-3, with two abstentions, to recommend FDA approval of the NovoTTF, novel device that blasts glioblastoma brain tumors

The device would be indicated for patients with glioblastoma multiforme (GBM) -- the most common primary brain tumor diagnosed in adults. The median survival for patients with GBM is just 15 months. Fewer than 10% of patients are alive five years after diagnosis.

Currently, GBM patients have a limited number of treatment options, including surgical resection -- when possible -- followed by radiation and chemotherapy. But the prognosis is almost uniformly bleak.

If the FDA followed the advice of the panel and approved the device, it would be an option for people with recurrent GBM who have exhausted surgical and radiation options. The panel felt the device should only be an option for patients who have tried chemotherapy.

The device is comprised of a four set of electrodes that are attached to a patient's shaved head, which are covered by what looks like a big white bandage. The device is powered by a 6 lb battery pack that is carried by the patient in an over-the-shoulder bag.

The following day, the same panel unanimously recommended approval of the investigational Pipeline Embolization Device to wall off large intracranial aneurysms in patients who are unlikely to respond to currently available treatments.

The panel voted 9-0 that the benefits of the device -- made by Menlo Park, Calif.-based Chestnut Medical Technologies -- outweigh its risks. The company is seeking an indication for the Pipeline Embolization Device for the endovascular treatment of large or giant wide-necked intracranial aneurysms in the cavernous and paraclinoid regions of the internal carotid artery.

In the company's trial, the device was 74% effective at achieving complete aneurysm occlusion.

If the FDA follows the advice of its advisory panel and approves the Pipeline device, it would offer patients with very large, hard-to-treat aneurysms a way to rid themselves of symptoms such as severe headaches and vision disturbances, and greatly lessen the risk of aneurysm rupture.

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Medicare Paid Millions for Viagra

Despite a rule that bars Medicare reimbursement for erectile dysfunction (ED) treatments, the Centers for Medicare and Medicaid Services (CMS) paid out $3.1 million for the drugs in 2007 and 2008, a new government report found.

Of the $3.1 million, $3 million went toward paying for (sildenafil) Viagra, according to the report prepared by the Department of Health and Human Services Office of the Inspector General.

The Medicare Modernization Act of 2007 stated that CMS wouldn't pay for "... a drug when used for the treatment of sexual or erectile dysfunction, unless such drug were used to treat a condition, other than sexual or erectile dysfunction, for which the drug has been approved by the Food and Drug Administration."

CMS will still pay for ED drugs to treat other conditions for which they are FDA-approved, such as pulmonary hypertension.

The ED prescriptions were erroneously paid for because CMS' Medicare Drug Data Processing System didn't have an updated list of excluded drugs, so it automatically approved the reimbursements for ED drugs prescribed for sexual or erectile dysfunction, the report said.

The government contracts with private insurers to administer Medicare Part D, the drug benefit, which is offered to those who are entitled to Medicare Part A or enrolled in Part B.The report authors recommended that CMS determine whether it can try to get the money back from the insurance companies that were paid by Medicare for providing ED drugs.

Recession Left Millions Uninsured

The economic recession left millions of Americans without health insurance, and even those with coverage have struggled to pay medical expenses, according to a new survey by the Commonwealth Fund.

About 52 million U.S. adults were uninsured at some point last year, a major increase from the 38 million who lacked insurance in 2001, according to survey.

Nearly one-quarter of working-age adults or their spouses -- 43 million people -- have lost their job in the past two years. Three in five people who lost a job with health benefits in the past two years (about nine million people) became uninsured, according to the survey.

The survey also found that medical expenses and insurance coverage have grown more expensive over the past decade. About 49 million working adults reported spending 10% or more of their income on out-of-pocket medical costs and on health insurance premiums, up from 31 million in 2001.

High costs led 75 million adults in 2010 to skip doctor visits, recommended tests or treatments and to not fill prescriptions.

The Affordable Care Act (ACA), once it's fully implemented in 2014, will provide insurance coverage to nearly all of those 52 million adults who didn't have coverage at some point in 2010, the report authors said.

Next Week

A number of groups are holding events next week to mark the one-year anniversary of when President Obama signed the Affordable Care Act (ACA) into law.

The Heritage Foundation on Monday will hold a discussion called "Why Doctors Need Full Repeal of Obamacare: Medical Professionals Diagnose the Law's Side Effects." The same day, the Cato Institute will hold a talk called "The New Health Care Law: What a Difference a Year Makes."

Two different business groups -- the Small Business Majority and the U.S. Chamber of Commerce -- will hold conference calls on Monday to discuss the law's impact on business.
