Pharma Companies to Tap Into Social Networking

BY ALICIA AULT

WASHINGTON — Pharmaceutical companies are turning to social networking sites to reach their customers—both physicians and patients—since it has become increasingly difficult to market their products using traditional approaches.

At a meeting sponsored by a Washington-based public relations company, Waggener Edstrom Worldwide, staffs from drug companies and public relations companies brainstormed on the best ways to maximize opportunities presented by social-networking sites such as Facebook and Twitter without running afoul of federal regulations.

The Food and Drug Administration has not determined how social networking fits into its regulatory construct. Sanjay J. Koyani, director of FDA Web communications, said that the agency was using social networking

tools to advance its own goals—for instance, with a Twitter page devoted to tweets (messages of 140 characters or fewer) about agency recalls—but that it is still working out how it would regulate messages presented by pharmaceutical companies.

Even so, the FDA tends to apply current regulations to digital communications, according to an analysis by Waggener Edstrom. Companies are required to present a fair balance between benefit and risk, and may not promote off-label uses.

Mark Gaydos, senior director of regulatory affairs at Sanofi-Aventis, is heading an informal task force of representatives from five drug makers seeking to create voluntary guidelines on the industry's use of social media.

The companies have had discussions with the FDA Division of Drug Marketing, Advertising, and Communications about their efforts, he said.

Analysts Predict Big Jump in Health Care Share of GDP

BY ALICIA AULT

WASHINGTON — Even as the economic downturn causes private health spending to slow, public sector health spending is rising, according to a federal analysis.

An estimated 3.4 million people may lose private health insurance coverage in 2009 and another 2.6 million may lose coverage in 2010, said Sean Keehan, an actuary at the Centers for Medicare and Medicaid Services' Office of the Actuary.

Total U.S. health care spending was an estimated \$2.4 trillion in 2008, which is an increase of 6.1% over 2007, according to the annual projection of health spending trends published online in the journal Health Affairs. This year, spending is expected to grow by only 5.5%.

That rate of growth is expected to far outpace the nation's gross domestic product in 2009. Economists for the CMS said they predict the GDP to shrink by 0.2% this year.

Meanwhile, the health care share of GDP is expected to grow 1.4%—the biggest annual jump as a portion of GDP since economists first started tracking this indicator in 1960, said Christopher Truffer, a CMS actuary. Health spending will account for 17.6% of the GDP in 2009, according to the report (Health Affairs 2009 Feb. 24 [doi:10.1377/hlthaff. 28.2.w346]).

The economists projected that overall health spending will rise by only 4.6% in 2010, thanks largely to the mandated 21% reduction in physician payments required under the Sustainable Growth Rate target set by Medicare.

However, since Congress usually eliminates the cuts or grants a fee increase every year, the CMS economists calculated some alternative scenarios. If payments were kept constant, Medicare spending would rise 6.4%, or 3.9% faster than if the cuts went into effect.

Medicaid spending will grow 9.6% in 2009, up from 6.9% in 2008. Private health insurance benefits spending grew an estimated 5.8% in 2008, but will rise only 4.1% in 2009.

The CMS projections make it seem like cost-containment efforts are having a negligible effect on restraining overall health spending. The economists said the Medicare fee cuts would make a difference, but that they did not have the data to calculate whether other cost-containment efforts in the private sector in particular were having any effect on restraining health spending.

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POLICY & PRACTICE

CMS Reopens CAS Review

The Centers for Medicare and Medicaid Services indicated that it has decided to take another look at whether or not it will cover carotid artery stenting for patients who are at high risk for the procedure because of anatomic risk factors and those who have asymptomatic carotid artery stenosis that is greater than 80%. The agency ruled against coverage in October, but said in opening the review that new evidence had come to light. The Society for Cardiovascular Angiography and Interventions praised the agency's decision, saying in a statement that coverage "would provide additional treatment options for a larger group of patients who are at risk for stroke." The CMS was prompted to reopen the decision after the publication of two new studies, CAPTURE 2 and EXACT, in the March issue of Circulation: Cardiovascular Interventions. Those trials show that symptomatic patients and asymptomatic patients having carotid artery stenosis achieved outcomes recommended by the American Heart Association. The agency noted that it expects to issue a preliminary decision by September and post the final ruling by December.

HEDIS to Include Aspirin Measure

The National Committee for Quality Assurance has proposed the inclusion of a new measure on the use of aspirin to prevent cardiovascular disease for its Healthcare Effectiveness Data and Information Set. According to the committee, a 2006 study found that aspirin "was one of the three most clinically and cost-effective preventive services." Healthcare Effectiveness Data and Information Set measures are used to evaluate the performance of health plans and providers. The committee said that the aspirin use would be measured through the Consumer Assessment of Healthcare Providers and Systems, which quizzes patients on their experiences. Data would be collected in 2009 but would not reported publicly until 2010.

Bill Preserves Ability to Sue

Several House members have introduced a bill that would guarantee consumers the ability to sue medical device makers for injuries. Rep. Frank Pallone (D-N.J.) and Rep. Henry Waxman (D-Calif.) introduced the Medical Device Safety Act shortly after the U.S. Supreme Court ruled in the Levine v. Wyeth case that drug makers are not immune from suits just because their products have the approval of the Food and Drug Administration. A companion bill was introduced by Sen. Ted Kennedy (D-Mass.) and Sen. Patrick Leahy (D-Vt.). The lawmakers said they are hoping to overturn a dissimilar ruling made by the court in February 2008 in Riegel v. Medtronic. In that suit, the justices

voted 8-1 that FDA approval conferred protection against litigation for devices. The Advanced Medical Technology Association said in a statement that it opposed the bill, because it would restrict patient access, it would have a chilling effect on innovation, and it would ultimately lead to more suits.

Device Makers Set Ad Principles

The Advanced Medical Technology Association has released guidelines that it said will make direct-to-consumer advertising for medical devices more accurate and useful for patients. The document sets out best practices for the dissemination of clear, balanced information to patients about innovations and for encouraging dialogue between patients and their physicians, the association claimed. The guidelines promote the use of consumer-friendly language, appropriate education of health care professionals prior to ad launch, and revision or withdrawal of ads if new information indicates a serious, previously unknown safety risk for a medical device. "We believe that direct-toconsumer advertising can be a powerful tool to educate patients about new technologies and treatment options when conducted appropriately," association chairman Michael Mussallem said in a state-

Boston Limits Tobacco Sales

Boston has banned tobacco-product sales at pharmacies—becoming the second city to do so-and on college campuses. The Boston Public Health Commission's board of health also banned new permits for smoking bars, such as hookah and cigar bars, and prohibited the sale of blunt wraps, a tobacco leaf that is often used to roll marijuana cigarettes. The board said it was working with pharmacies, health centers, and hospitals in the city to increase people's access to smoking cessation resources. Last year, San Francisco imposed the first municipal ban on the sale of cigarettes by pharmacies. Many college campuses already ban tobacco.

Metabolic Drugs Top List

Medications that affect a person's metabolism by lowering cholesterol, controlling diabetes, and trimming weight accounted for \$38 billion of the \$208 billion that American adults spent on drugs in 2006, according to a report on prescription drugs issued by the Agency for Healthcare Research and Quality. Cardiovascular drugs accounted for \$33 billion; central nervous system drugs cost \$28 billion; psychotherapeutic drugs cost more than \$17 billion; and hormones cost \$14 billion. The agency found that spending for outpatient prescription analgesics increased from about \$4 billion in 1996 to more than \$13 billion in 2006.

—Alicia Ault