POLICY & PRACTICE

FDA to Regulate Tobacco?

It seemed like back to the future in Washington on Feb. 15, when Sen. Edward M. Kennedy (D-Mass.) presided at a press briefing announcing a proposal that would give the Food and Drug Administration the authority to regulate cigarettes as a drug delivery device. In the mid-1990s, Dr. David Kessler, then FDA commissioner, made a bid to do just that, but lost in a battle that ended at the Supreme Court. Since that time, congressional bids to extend FDA's purview have failed. Sen. Kennedy declared that 2007 is the lucky year. "The likelihood of passage is extremely high," he said of his bill, which according to cosponsor Sen. John Cornyn (R-Tex.) already has 30 allies, 11 of them Republicans. Rep. Henry Waxman (D-Calif.), introducing the House companion bill, agreed that, "this is the year it will become law," noting that 100 of his colleagues are ready to sign on. The bill would give FDA more power to restrict tobacco ads and sales to children in particular, require reduction of nicotine levels, and necessitate bigger and more informative warnings on tobacco products. FDA could not ban nicotine-containing products. President George W. Bush has not shown support, but Sen. Cornyn said he'd encourage him to sign it into law if the bill passes the House and Senate.

HEART for Women Reintroduced

The American Heart Association is throwing its weight behind the Heart Disease Education, Analysis and Research, and Treatment (HEART) for Women Act, which was reintroduced in both the House and Senate last month. Sponsored by Sen. Debbie Stabenow (D-Mich.) and Sen. Lisa Murkowski (R-Alaska), the legislation authorizes the Health and Human Services department to provide education to older women and health care professionals on the diagnosis and treatment of women with heart disease, requires gender-specific reporting of heart disease data to the federal government, and expands WISEWOMAN (Well-Integrated Screening and Evaluation for Women Across the Nation), the free heart disease and stroke screening program, beyond its current 14 states. The legislation also is backed by the Society for Women's Health Research, WomenHeart: the National Coalition for Women with Heart Disease, and the Association of Black Cardiologists Inc.

Cardio Tops Drug, Hospital Costs

New data from the Agency for Healthcare Research and Quality show that drugs for cardiovascular disorders are the most costly and that heart disease, stroke, and other circulatory conditions account for one in six hospitalizations. Americans spent $32 billion on drugs for cardiovascular conditions in 2004. The two biggest categories were cardiovascular drugs ($17 billion) and cholesterol-lowering drugs ($10 billion). Although 44% of adults bought a central nervous system drug, compared with 38% buying a cardiovascular drug and 22% a cholesterol cutter, spending for CNS drugs was only $7 billion. Circulatory system diseases put 7 million people in the hospital in 2004. The most common reasons: atherosclerosis (1.2 million stays), congestive heart failure (1.1 million), nonspecific chest pain (846,000), heart attack (695,000), and irregular heart beat (694,000).

FDA's $2 Billion Budget

The Bush administration is requesting $2.1 billion for the FDA in fiscal 2008, a 5% increase from the previous year's request. The agency still has not received its final appropriation for fiscal 2007, so the exact amount it will receive for that year is not known yet. The budget includes $444 million in user fees from industry, including a new program to charge generic drug makers fees to review their products. The agency estimates that generic companies will contribute $16 million in fiscal 2008. In a statement, Generic Pharmaceutical Association CEO Kathleen Jaeger said the decision to seek user fees "will not bring generic medicines to consumers faster as long as brand companies are still permitted to use tactics that delay market entry." The budget also includes $11 million for improving drug safety (this does not include user fee funds that also will go to that effort) and $7 million to boost medical device safety and to speed up device review. The agency also is requesting $13 million to move about 1,300 employees of the Center for Devices and Radiological Health to offices at the FDA's new White Oak, Md., campus. The FDA gradually has been moving its operations to the new facilities. The Washington-based consumer-, patient- and industry-supported Coalition for a Stronger FDA said the budget did not go far enough. It is seeking at least $175 million more, including greater increases for food, drug, and medical device safety.

Medicare Generic Drug Use Rises

The Centers for Medicare and Medicaid Services says that generic drugs accounted for 60% of the prescriptions dispensed to people who receive benefits through either Part D or Medicare Advantage plans for the first three quarters of 2006. Generic drug use among Part D enrollees is 13% higher than it is for Americans who receive benefits through private payers, said the CMS. The agency said that in 2006, generics accounted for 53% of prescriptions dispensed to privately insured Americans. Greater use of generics will translate into lower costs for the Part D program and possibly expanded coverage for beneficiaries, according to the CMS. "We will continue to promote generics where they are available as an important strategy to keep the new drug benefit affordable over the long term," CMS Acting Administrator Leslie V. Norwalk said in a statement.

—Alicia Ault

Physicians Are Split on the Ethics of Free Drug Samples

BY PATRICE WENDLING
Chicago Bureau

TUCSON, ARIZ. — Physicians are divided over whether it is ethical to use free sample medications in their primary care practices, Nancy Sohler, Ph.D., and Dr. Diane McKee reported at the annual meeting of the North American Primary Care Research Group.

Accepting samples was viewed either as being ethically questionable or as a useful way of helping provide health care to low-income patients, according to findings from a study of 24 family medicine and general internal medicine physicians, nurses, and administrators in practices affiliated with a large urban medical center serving low- and middle-income patients in New York.

Interactions with pharmaceutical representatives were viewed as a direct conflict of interest, an influence that could be controlled, or a source of useful information that helped keep the practice up to date on new medications. Of the total, 10 respondents felt that they could control the influence of drug firm representatives by keeping them away from residents, by setting limits on what gifts or favors could be accepted, or by always being mindful that representatives are selling a product, Dr. Sohler said in an interview.

For the respondents who drew a hard ethical line, "it wasn't that they thought giving out samples [to patients] was unethical, but that it wasn't good practice," she said. "They understood why others did it, but they worried about conflicts of interest with their interactions with the reps."

Those who accepted samples said inadequacies in the health care system forced them to rely on gifts to care for their most needy patients.

All the respondents evaluated marketing practices from the perspective of protecting and serving their patients, said Dr. Sohler, professor of community health and social medicine, City University of New York, New York. No one was concerned that physicians were ignoring clinical symptoms to prescribe the "right drugs."

The study included in-depth, qualitative interviews and was prompted by an administrative decision at the medical center to ban samples and pharmaceutical representatives from the community practices. That decision left many providers uncertain about how to care for patients without adequate health care coverage. Others suggested that the policy was changed because the administration didn't want physicians taking the time to talk to sales representatives, didn't trust that staff would avoid entering into agreements with pharmaceutical firms, and did want a single policy, because teaching sites had a "no-rep" policy and other sites didn't need samples. ■

NPI Sign-Up Deadline Is May 23

The clock is ticking for physicians to sign up for a National Provider Identifier, the new 10-digit number that will be used by Medicare, Medicaid, and many private health plans to process claims.

The deadline for registering for an NPI number is May 23.

Physicians who are not using an NPI after that date could experience cash flow disruptions, according to the Centers for Medicare and Medicaid Services.

The transition to a single identifier that can be used across health plans is required under the Health Insurance Portability and Accountability Act (HIPAA) of 1996. Most health plans and all health care clearinghouses must begin using NPIs to process physicians' claims in standard transactions by May 23. Small health plans have another year to become compliant.

"The NPI is the new standard identifying number for all health care billing transactions, not just for billing Medicare or Medicaid. National standards … will make electronic data exchanges a viable and preferable alternative to paper processing," said Aaron Hase, a CMS spokesman.

As of Jan. 29, more than 1.6 million NPIs had been assigned, according to CMS.

Physicians and other health care providers can apply for an NPI online or by using a paper application. In addition, organizations like hospitals or professional associations can submit applications for several physicians in an electronic file.

Officials at CMS are urging physicians who haven't yet signed up to do so soon. A physician who submits a properly completed electronic application could have his or her NPI in 10 days. However, it can take 120 days to do the remaining work to use it, Mr. Hase said. The preparation includes working on internal billing systems; coordinating with billing services, vendors, and clearinghouses; and testing the new identifier with payers, he said.

So far, the process of obtaining an NPI has been relatively easy, said Brian Whitman, senior analyst for regulatory and insurer affairs at the American College of Physicians. The application process itself takes only about 10 minutes, he said.

But one thing to be aware of is that you may already have an NPI. Because some large employers may have already registered their providers, physicians may be surprised to learn that they already have a number, Mr. Whitman said.

As the May deadline approaches and more and more physicians get registered, the next question is how widely CMS plans to disseminate the NPIs. CMS officials have said they are considering creating some type of directory of NPIs that could be available to physicians and office staff.

—Mary Ellen Schneider

Physicians can apply for an NPI online at https://nppes.cms.hhs.gov or call 800-465-3203 to request a paper application.