Congress Weighs Giving FDA More Authority

BY JOYCE FRIEDEN
Associate Editor, Practice Trends

WASHINGTON — Congress is considering giving the Food and Drug Administration more authority over the pharmaceutical companies it deals with, but some legislators are warning against doing too much too fast.

"Changes to drug safety … must be carefully considered to make sure they don't unduly impact patient access," Sen. Mike Enzi (R-Wyo.), chair of the Senate Health, Education, Labor, and Pensions Committee, said at a hearing on FDA oversight. "Congress needs to engage in strong oversight to maintain public confidence in the FDA."

Sandra Kweder, M.D., deputy director of the Office of New Drugs at the FDA's Center for Drug Evaluation and Research, told the Senate committee that in order to ensure drug safety, it would be helpful if the FDA had more clout. She noted that it took a lot of back-and-forth haggling just to get some earlier warnings added to the label.

"The most important lapse [with the safety concerns surrounding Vioxx] was the delay it took to get the information into the labeling; it took over a year," she said.

The most important lapse with safety concerns with Vioxx was the delay it took to get information into the labeling; it took longer than 1 year.

The committee's ranking member, Sen. Edward Kennedy (D-Mass.), also spoke in favor of giving the agency greater labeling authority. "The FDA needs clear authority to require relabeling of a drug after approval once a risk is found," he said. "Negotiations with the drug company should never delay [that]."

Some observers said that although giving the agency more authority over label changes is a good idea, it only goes so far. "We all know product labeling does not change provider behavior very much," said Arthur Levin, director of the Center for Medical Consumers in New York and the consumer representative on the FDA's Drug Safety and Risk Management advisory committee. Even if FDA does get more labeling authority, "we shouldn't count on it protecting the public from harm," Mr. Levin said at a teleconference announcing the release of a new survey on consumer attitudes toward the FDA.

The survey of 1,000 adults nationwide was performed by pollster Celinda Lake and sponsored by a coalition of consumer groups. The results showed that only 14% of respondents had a great deal of confidence in the agency's ability to ensure the safety of prescription drugs. And 48% of respondents believed the FDA was too influenced by the industries over which it has jurisdiction.

Another subject discussed at the Senate hearing was the secrecy of clinical trial data. "I'd like to emphasize the importance of open access to data from clinical trials, including negative trials and unpublished research," said David Fassler, M.D., a child and adolescent psychiatrist in Burlington, Vt., who testified on behalf of the American Academy of Child and Adolescent Psychiatry and the American Psychiatric Association.

In 2004, when Dr. Fassler testified on the question of whether there was a link between selective serotonin reuptake inhibitors (SSRIs) and suicide, "there were only four studies in the published literature on [the use of] SSRIs in adolescents. But I later learned that there were 11 unpublished studies whose results had been submitted to FDA." ■

Incremental Changes Called Key to Health Care System Reform

BY JOYCE FRIEDEN
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WASHINGTON — Consumer-driven health care may be all the rage right now, but there's no single cure for the nation's ailing health care system, several experts said at a health care congress sponsored by the Wall Street Journal and CNBC.

"There are no silver bullets," said Douglas Holtz-Eakin, Ph.D., director of the Congressional Budget Office (CBO). "There is no single item—technology, disease management, tort law—that is likely to prove to be the answer to aligning incentives, providing high-quality care at reasonable costs, and financing it in a way that's economically viable. More likely, we'll have a series of incremental changes" that will shore up the system.

"Rising health care costs represent the central domestic issue at this time," Dr. Holtz-Eakin said. For example, over the next 50 years, if nothing is done, "the cost of Medicare and Medicaid will rise from 4% of the gross domestic product to 20%—the current size of the entire federal budget."

Robert Reischauer, Ph.D., a former CBO director who is now president of the Urban Institute, noted that Medicare was a particular concern, since Medicare spending is expected to grow very rapidly over the next 10 years. He listed four possible solutions for the Medicare budget crisis.

The first possibility is to reduce the scope of coverage, but "that isn't a practical course of action," he said. "All forces are moving in just the opposite direction."

Another option is to restrain the growth in payments to providers, but already, Medicare is considered "not too generous," compared with private payers, since it pays on average only about 80% of the private rate. "[Payment restraint] is clearly not going to happen," he said.

The third option is to make beneficiaries pay more for care in the form of higher premiums, deductibles, and cost sharing.

"Some people think that will cause beneficiaries to purchase more rationally and cut out low-value services, but we have to remember, the vast bulk of spending is on individuals who are very sick, have many chronic conditions, and aren't in a position to comparison-shop," he said. "Moreover, the services that they're purchasing are extremely complex and confusing, and providers play a very significant role in determining the demand for and type of services received by beneficiaries.

"Before we bet the ranch on this approach," he continued, "we're going to have to see what happens to spending patterns among the under-65 population as they are faced with high-deductible plans, health savings accounts, consumer-driven health plans, and other approaches to incentivize them to purchase more rationally. If this proves to be a successful approach for the under-65 population, one can see it gradually angling into the bag of tools that Medicare has."

However, Dr. Reischauer noted, the potential for shifting more costs onto beneficiaries is limited, "because they already spend a considerable amount of their incomes on Medicare cost-sharing of one sort or another. By 2025, the average 65-year-old Medicare beneficiary will be paying more than the size of their Social Security check in cost-sharing and deductibles."

A fourth approach is to restructure Medicare in ways to generate competition among providers, Dr. Reischauer said. This would mean emphasizing technologies that improve efficiency, such as electronic health records and electronic prescribing. It also would involve decreasing the volume of unneeded services being provided.

Gail Wilensky, a former administrator of the Centers for Medicare and Medicaid Services who is now a senior fellow at Project HOPE, in Bethesda, Md., expressed disappointment that Congress did not do more to address the issue of rising costs when it passed the Medicare Modernization Act of 2003.

That law "is a good example of eating dessert first," she said. "There was an opportunity to try and slow down spending in a significant way while a new benefit was being introduced, but primarily, what [the law] does is provide a new benefit and some additional payments to providers of services, but not very much in terms of trying to restructure Medicare for the future."

One little-known provision of the law does attempt to address the cost issue, she added. "Starting in 2007, Part B will be much more related to income. The subsidy will start declining significantly for those with higher incomes. As the baby boomers begin to retire, some of them with higher incomes and assets, this is at least one opportunity" to help with the cost problem.

"A couple of weeks ago, [Rep.] Bill Thomas [R-Calif.] talked about the need to think about Social Security and Medicare together. Both represent transfers from the working population to the dependent, nonworking population. To begin thinking about this as a joint issue may allow us to make more sensible decisions," she said.

For example, Americans should consider "how we can change both fiscal policies and cultural expectations so our whole concept of retirement begins to … reflect the increasing longevity and, for many individuals, the increased well-being and health status they have at age 65 relative to what 65 meant when Medicare was introduced in 1965," she said. "We need to think about fiscal policies to encourage continued labor force participation for people at 65 and 70." ■

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