Court Says FDA Approval Offers No Liability Haven

BY ALICIA AULT

In an eagerly anticipated opinion, the U.S. Supreme Court has upheld a lower court ruling that Food and Drug Administration approval does not give pharmaceutical companies immunity from product liability lawsuits.

The justices voted 6-3 to affirm the judgment of the Vermont Supreme Court that federal law did not preempt Diana Levine's claim of inadequate warning on the label of promethazine (Phenergan). Ms. Levine received the drug by intravenous push and subsequently lost her arm. She was awarded $6.7 million by a Vermont jury.

A majority of justices rejected the argument by Wyeth Pharmaceuticals Inc., maker of Phenergan, that it was impossible for the company to simultaneously comply with both federal and state laws and regulations.

Wyeth could have unilaterally strengthened the label at any time without input or clearance from the FDA, wrote the justices, concurring with the lower court opinion. And, the company's argument that following the duty to warn under state law would have interfered with the FDA's power to preempt state law was "meritless," according to the majority opinion.

Justice Clarence Thomas voted with the majority, agreeing that Wyeth could have changed its label and complied with both state and federal laws. But he said that he did not agree with the majority's more far-reaching conclusions about preemption, specifically a tendency to override state laws when they were perceived to be an impediment to enforcing federal statutes.

Justice Samuel Alito and Justice Antonin Scalia, joined by Chief Justice John Roberts, dissented, writing in their opinion that "this case illustrates that tragic facts make bad law. The Court holds that a state tort jury, rather than the Food and Drug Administration, is responsible for regulating warning labels for prescription drugs." That premise is not consistent with previous rulings, they wrote.

Indeed, just last year the U.S. Supreme Court ruled in *Riegel v. Medtronic Inc.*, that FDA approval conferred special protection against product liability suits involving medical devices.

The Pharmaceutical Research and Manufacturers of America said that it was still reviewing the opinions in *Wyeth v. Levine*. "We continue to believe that the expert scientists and medical professionals at the FDA are in the best position to evaluate the voluminous information about a medicine's benefits and risks and to determine which safety information to include in the drug label," PhRMA Senior Vice President Ken Johnson said in a statement.

Consumer advocacy group Public Citizen called the ruling a broad rebuff to the industry's attempt to duck tort damages. Brian Wolfman, director of Public Citizen Litigation Group, said that the organization was "extremely gratified" that the Court "upheld the traditional right of patients harmed by defective and mislabeled drugs to sue drug companies to recover compensation for their injuries." ■

Bundled Hospital-Postdischarge Payment Fee Proposed by Obama

BY ALICIA AULT

If President Barack Obama sways Congress with his plans for health reform, hospitals and health providers would receive a bundled payment for care provided in the hospital and during the first 30 days after discharge.

The proposal was submitted as part of the president's budget "blueprint" in late February. A full budget plan is expected to be released some time this month. It's a long way from there to the proposal's becoming law; in some cases, proposals will require congressional action, while in others, they will be accomplished through federal rule making. Even so, this is not the first time that bundling has been mentioned as a cost-saving mechanism for federal health programs.

The Medicare Payment Assessment Commission (MedPAC) backed bundled payment in its June 2008 report to Congress, and the Centers for Medicare and Medicaid Services (CMS) began a 3-year, five-hospital demonstration project of the concept in January.

Along with bundling payments, the Obama budget also proposed paying less to hospitals with high readmission rates during the 30-day postacute period. The combination of bundling pay and reducing payments should save "roughly $26 billion of wasted money over 10 years," according to the budget blueprint. That money would be contributed to the $600 billion reserve fund dedicated to financing health reform.

There were few other details offered by the administration. But in December, the Congressional Budget Office analyzed a proposal to bundle payments and estimated that it would create $950 million in savings from 2010 to 2014.

In a note to clients after the blueprint release, experts at Washington Analysis Corp. who follow health policy said, "We expect Congress to consider this idea, especially since this concept has been put forward for several years by CMS, MedPAC and others."

Washington Analysis said that it also expected to see a proposal to penalize hospitals for high readmission rates. ■

POLICY & PRACTICE

IOM: Health Coverage Is Essential

Health insurance, not just safety net access to care, is essential for people's health and well-being, an Institute of Medicine committee reported. Yet even if people have insurance, those living in areas where many others aren't covered find it more difficult to get needed care and have decreased satisfaction with their care, the panel found. Its report called on lawmakers to approve and implement universal health coverage while reducing costs and the rate at which health care spending is rising. The findings show that the societal consequences of having large numbers of uninsured Americans are growing, said Dr. Risa Lavizzo-Mourey, president and CEO of the Robert Wood Johnson Foundation, which provided funding for the work. "People without insurance do not get the care they need, and too many people live sicker and die sooner as a result," Dr. Lavizzo-Mourey said in a statement.

Physicians Postponing Retirement

Fewer physicians left group practices in 2008 than in 2007, and a majority of group practice leaders believe that the change reflects more physicians delaying retirement because of the poor economy, said the American Medical Group Association. The group's annual survey of AMGA members reported about a 6% turnover of group practice physicians in 2008, compared with nearly 7% in 2007. The top reasons cited for leaving a group included poor fit with one's practice and need to relocate to be closer to family. Flexibility can keep physicians in a practice, according to respondents, nearly half of whom said part-time options encourage physicians to stay while meeting personal needs or to delay retirement. Almost three-quarters of group practices offer preretirement physicians reduced hours, 56% allow for no call responsibility, and 20% allow for concentration on certain patient groups.

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 disseminating clear, balanced information to patients about innovations and for encouraging dialogue between patients and their physicians, the association claimed. The guidelines promote 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 DTC advertising can be a powerful tool to educate patients about new technologies and treatment options when conducted appropriately," said the association's chairman, Michael Mussallem, in a statement.

87 Million Uninsured 2007-2008

Nearly 87 million Americans—1 out of 3 people under age 65—were uninsured at some point during 2007-2008, according to a report from the advocacy group Families USA. More than half of individuals and families with incomes between the federal poverty level and twice the poverty level—between $21,200 and $42,400 in annual income for a family of four in 2008—went without health insurance at some point in 2007-2008, the report said. In addition, most of those who went uninsured did so for periods: Almost two-thirds were uninsured for 9 months or more. Four of five of the uninsured were in working families, and most of these families included someone employed full time, the report said.

Aetna Offers Money-Saving Tips

The health insurer Aetna said it can help physicians pinch pennies in these tough economic times. The company estimated that physicians who use its free online tools for billing and administrative tasks could save up to $20 per patient visit. The figure assumes electronic transactions for eligibility and benefits inquiries, claim submissions, claim-status inquiries, remittances and funds transfers, and precertifications. For example, the cost to make an eligibility and benefits inquiry by phone or paper would be $3.70, compared with 74 cents electronically, according to Aetna. The savings are even greater for precertification, which costs more than $10 by paper or a phone conversation and about $2 when done electronically. Aetna's electronic tools are available at the company's secure provider Web site. More information is available through Aetna's automated phone service or online at www.aetna.com/provider.

Group Wants Ban on Industry CME

The consumer watchdog group Public Citizen has asked the American Medical Association to support a total ban on commercial support of continuing medical education. In a letter to the chairs of the AMA's ethical and CME councils, Public Citizen's Health Research Group said that it supported the ban "because the consequences of any corrupting influence of commercial support on CME are so significant." The group chose the AMA, because, "as the voice of organized medicine, the AMA is well positioned to lead a reform effort," said the letter. "Physician-supported CME" is a viable alternative to commercial funding, said the group. The Pharmaceutical Research and Manufacturers of America said in a statement that a ban on commercial support of CME could prevent physicians from accessing critical information about treatments.

—Jane Anderson