POLICY & PRACTICE

Kaufman Begins NDEP Post

Dr. Francine R. Kaufman recently began a 3-year term as chair of the National Diabetes Education Program. Jointly sponsored by the National Institutes of Health and the Centers for Disease Control and Prevention, the program provides free diabetes information to health care providers and patients. "It is with immense pleasure that I welcome Dr. Kaufman, a proven leader in the diabetes community, who will focus on disseminating materials and continuing and building on partnerships to improve diabetes prevention and care," said Dr. Griffin P. Rodgers, director of the National Institute of Diabetes and Digestive and Kidney Diseases. Dr. Kaufman, who has served on NDEP advisory committees since 2000, is director of the comprehensive childhood diabetes center and head of the center for endocrinology, diabetes, and metabolism at Children's Hospital Los Angeles.

Poor Marks for 2007 PQRI

Most physicians who participated in Medicare's 2007 Physician Quality Reporting Initiative found the program at least moderately difficult, according to a survey conducted by the American Medical Association. Only 22% of respondents to the online survey were able to successfully download their feedback report. Of those who downloaded the report, less than half found it helpful. In an open-ended question about their experience with the program, nearly all the responses were negatives, according to the AMA. The results are based on responses from 408 physicians. The AMA plans to work with Congress and the administration to alter the program to provide physicians with interim feedback reports. A recent survey from the Medical Group Management Association reported similar problems in accessing feedback reports.

Many Have Drug 'Gap' Coverage

A total of 13% of Medicare beneficiaries enrolled in Part D prescription drug plans and 63% of those in Medicare Advantage plans with prescription benefits had some form of coverage in the "doughnut hole," or coverage gap, according to a Centers for Medicare and Medicaid Services study on Part D drug claims. The study, which included data on Medicare drug claims for the 25 million Part D beneficiaries, also indicated that the vast majority of enrollees used the drug benefit: In the program's first year, 90% of enrollees filled at least one prescription. In addition, the use of generic drugs has been high in Part D, rising from 60% in 2006 to nearly 68% in the first quarter of this year.

Behavioral Paths Aid Weight Loss

Obese school-aged children and teenagers can lose weight or prevent further weight gain if they participate in medium- to high-intensity behavioral management programs, according to a study by the Agency for Healthcare Research and Quality. Effective programs taught techniques to improve dietary and physical activity habits, with some using strategies such as goal setting, problem solving, and relapse prevention. These programs met for a total of more than 25 hours, usually once or twice a week, for 6-12 months. Researchers found that after completing weight management programs, obese children would weigh 3-23 pounds less, on average, than would those who were not involved in the programs. The weight difference was greatest among heavier children as well as those enrolled in more intensive programs, and weight improvements were maintained for up to 1 year after the program ended, the AHRQ study found.

More Join Consumer-Directed Plans

The number of people enrolling in consumer-directed health plans rose 25% from last year, according to a survey of nearly 2,800 private insurance enrollees by the Blue Cross and Blue Shield Association. The survey also found that consumers in CDHPs are more cost conscious than are non-CDHP consumers; they are 30% more likely to track their health expenses than are those in more traditional health insurance plans, and 27% more likely to ask their doctors about the cost of treatment. "[CDHP] consumers are demonstrating more active engagement in their own health care than are non-CDHP consumers, as evidenced by an increased use of health and wellness programs and better tracking, estimating, and budgeting" for health care costs, said Maureen Sullivan, senior vice president for strategic services at BCBSA. The 39 independent Blue Cross and Blue Shield companies serve a total of 4.4 million CDHP enrollees—a 50% increase from last year.

Pharmaceutical Sales Outlook

The U.S. pharmaceutical market is expected to grow 1%-2% in 2009, resulting in sales of about $292-$302 billion, according to analysis from the health care market research firm IMS Health. This latest projection is down from the 2%-3% increase projected by IMS earlier this year, and reflects the expected impact of patent expirations, fewer launches of new products, and the slowing U.S. economy. Worldwide pharmaceutical sales are expected to grow 4.5%-5.5% in 2009, similar to growth this year. "The market will continue to contend with a number of forces—among them the shift in growth from developed countries to emerging ones, specialist-driven products playing a larger role, blockbuster drugs losing patent protection, and the rising influence of regulators and payers on health care decisions," Murray Aitken, senior vice president of Healthcare Insight at IMS, said in a statement.

—Joyce Frieden

LAW & MEDICINE

Pharmaceutical Preemption

Ever heard of the doctrine of preemption? It is the notion of a state law being "wiped out" by a law the federal government has created. That is, even if a state already has a law that is quite similar to a law enacted by Congress, if the Congress clearly says that it is in control, then the state's law is preempted by the federal law.

BY MILES J. ZAREMSKI, J.D.

Preemption plays a large part in a case involving the pharmaceutical industry—one that has made it all the way to the U.S. Supreme Court, which heard oral arguments on Nov. 3. The case is called *Wyeth v. Levine*.

The facts of the case are straightforward and sad. Diane Levine was a guitarist and songwriter from Vermont who went to a local clinic, seeking relief from migraine headaches and the accompanying nausea. As part of her treatment, she was twice injected with the antinausea drug promethazine (Phenergan), made by Wyeth. The first injection, given intramuscularly—the preferred method—was uneventful; however, she did not get relief from the nausea, and returned to the clinic later that day for further treatment. She was given Phenergan again, this time by the intravenous-push method. Unfortunately, the medication from that injection ended up in an artery, causing gangrene to develop and resulting in the amputation of her right forearm. Her musical career was over.

She sued the clinic and its personnel for malpractice in state court, and settled with them for $700,000. She also sued Wyeth under state products liability law on the theory that Wyeth should have prohibited the intervenous-push method, and therefore failed to properly strengthen its labeling. She also claimed that the drug became a defective product as a result.

Ms. Levine's lawsuit is in accord with most states' laws that allow lawsuits against drug companies by consumers if the companies fail to warn consumers about drug hazards that are not obvious. Wyeth asserted that the Food and Drug Administration (FDA) had previously approved the intervenous-push method, knowing that it could result in gangrene if injected incorrectly, and that there was no new information about that risk to add to the label.

Although it is true that the FDA did approve this method of application for Phenergan as medically appropriate in some circumstances, a Vermont state court jury disagreed; it awarded Ms. Levine $6.7 million. The case was then appealed to the Supreme Court, where the main issue to be decided is whether patients can sue drug manufacturers under state law if the FDA has already approved the drug and is aware of its risks.

In a case before the Supreme Court earlier this year, *Riegel v. Medtronic, Inc.*, the country's highest tribunal ruled by an 8-1 vote that where the FDA had reviewed and approved (class III) medical devices, such as pacemakers, state lawsuits are preempted—even if those devices are shown to be ineffective or defective—so long as the device manufacturer complied with federal requirements. Of interest was a comment by Associate Justice Antonin Scalia, who wrote the opinion, in reference to earlier cases involving the Dalkon Shield intrauterine device which was withdrawn from the market because of serious complications in some users: The "Dalkon Shield failure and its aftermath demonstrated the inability of the common law tort system to manage the risks associated with dangerous devices."

Although the Dalkon Shield case does not address the issue of discovery of flaws to a device that become known after the FDA approves it, this decision may prove effective precedent for how the court decides *Levine*.

The *Levine* case has drawn considerable attention because it throws the spotlight not only on the cornerstone notion that if someone gets hurt because of a bad product, that individual can sue to recover damages, but how, and when, the federal government can preempt what otherwise is a right based upon a state's products liability law to sue when a wrong has occurred. To put it in a slightly different context, consumer advocates argue (as they did in supporting briefs filed with the Supreme Court in *Levine*) that drug companies want to be immunized from liability lawsuits by hiding behind the "skirts" of FDA regulations that they comply with—that is, if the FDA sanctions a drug for use, the drugmaker should be free of liability, even if harm results from its use or administration.

In the end, the *Levine* case presents a clear-cut choice: between a drug manufacturer claiming protection because its drug survived FDA scrutiny, versus state tort and product liability laws designed to protect the health and welfare of its citizens when they are injured by those very same pharmaceuticals because of the product being defective or inadequately labeled. Hopefully, there will be wisdom and equity in the decision rendered by the Supreme Court. ■

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