Policy & Practice

Von Eschenbach Confirmed

Almost 9 months after he was first nominated to be Food and Drug Administration commissioner, Dr. Andrew von Eschenbach was finally confirmed by the Senate by an 80-11 vote in the wee hours of the 109th Congress. Confirmation came after an 89-6 vote to limit debate on his nomination. The naysayers included Sen. Chuck Grassley (R-Iowa), who has been one of Dr. von Eschenbach's most vocal critics. As Finance Committee chairman, he and his staff have been investigating what they call an inappropriate approval of Ketek (telithromycin). Sen. Grassley maintains that Dr. von Eschenbach has stonewalled committee investigators, and in an agitated floor statement during the nomination vote, he accused the nominee of hiding documents and intimidating FDA employees who dissented. Sen. Grassley warned his colleagues that Dr. von Eschenbach was a prime illustration of concerns about the lack of Senate oversight of the Bush administration. "I believe we need to send a message to the executive branch that it's not okay to impede congressional investigations. It's not okay to limit the Senate's access to documents, information, and employees of the executive branch," the senator said.

Liability Issues Have Impact

Many obstetricians report making changes to their practices out of fear of being sued for malpractice, according to a survey conducted by the American College of Obstetricians and Gynecologists. About 37% of ACOG members surveyed said they had increased the number of cesarean deliveries they perform, while 33% reported decreasing the number of high-risk obstetrics patients that they care for and no longer offering vaginal birth after cesarean. More than 8% of respondents said they had stopped practicing obstetrics because of the risk of liability claims and more than 7% reported that they stopped doing so because of the lack of affordable or available liability insurance. "Medical lawsuit abuse continues to wreak havoc on physicians across America, and today fewer and fewer ob.gyns. are available to provide prenatal and delivery care, routine gynecological care or major gynecologic surgery," Dr. Douglas W. Laube, ACOG president, said in a statement. The survey covers January 2003 through December 2005. ACOG commissions a survey on medical liability experience every 2-4 years. The most recent survey included members for all 50 states, the District of Columbia, and Puerto Rico and had a 37% response rate.

Abortion Refusal Clause Upheld

Abortion opponents scored a victory last month when a federal appeals court upheld a statute that prohibits federal, state, and local governments that receive federal funds from discriminating against providers and insurers that refuse to provide abortion services. The provision, known as the Weldon Amendment, was enacted in December 2004. The law was challenged in court by the National Family Planning and Reproductive Health Association shortly after its passage and the provision was upheld by a federal district court last year. A federal appeals court rejected the National Family Planning and Reproductive Health Association's appeal on the grounds the group lacked standing and that no actual injury had occurred.

Hormone-Compound Regs Urged

The Food and Drug Administration should conduct surveys of the purity and dosage accuracy of bioidentical hormone compounds, according to a new policy adopted by the American Medical Association at its interim meeting last month. These compounds are often used by women in place of Food and Drug Administration–approved hormone preparations for replacement therapy, according to the AMA. The new policy also calls for mandatory reporting by drug manufacturers, including compounding pharmacies, of adverse events from bioidentical hormone usage. The FDA also should require standard patient information on packaging of compounded bioidentical hormone products, according to the policy. The AMA also noted that the term "bioidentical" should not be used unless the compound has been approved by the FDA. "There is no scientific basis for claims that compounded hormone therapies have a different risk-benefit ratio than FDA-approved hormone replacement therapies," Dr. Ardis Hoven, an AMA board member, said in a statement.

Plan B Court Battles Continue

Despite the FDA's recent approval of over-the-counter sales of Plan B emergency contraception for women aged 18 years and older, the Center for Reproductive Rights is continuing its court battle over the product. In the latest chapter in this continuing legal saga, a U.S. magistrate ruled that the Center for Reproductive Rights can subpoena White House documents as part of its lawsuit. The group is suing the FDA for failing to make Plan B available over the counter for women of all ages. The group filed the lawsuit in 2001 and has already deposed some current and former top FDA officials. As a result of this latest ruling, the group plans to subpoena communications between the Domestic Policy Office of the White House and select employees of the FDA that occurred between April 2003 and September 2006 that relate to Plan B.

—Mary Ellen Schneider

Jury Is Out on 'Health Courts' To Settle Malpractice Suits

BY ALICIA AULT
Associate Editor, Practice Trends

WASHINGTON — The concept of using administrative law judges instead of civil jury trials to settle malpractice suits has gained some admirers in the U.S. Congress and generated interest among state legislatures. But it is uncertain whether such a system is the solution to skyrocketing malpractice premiums and jury awards, according to academics, attorneys, and consumer and legislative representatives who met at a meeting sponsored by Common Good and the Harvard School of Public Health, Boston.

Under the "health court" concept, fleshed out earlier this year by Michelle Mello and David Studdert of Harvard, specially trained judges would make compensation decisions according to whether an injury was "avoidable" or "preventable" (Milbank Quarterly 2006;3:459-92). The plaintiff would have to show that the injury would not have happened if best practices were followed. Impartial experts would help set compensation, based on scientific evidence and what is known about avoidability of errors. Decisions would be made quickly.

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Such a system would likely increase the number of people eligible for compensation, but decrease the size of awards, Ms. Mello said.

Unlike the current tort system, a health court system could also help deter medical errors by collecting data that would then be given back to hospitals and practitioners for root-cause analyses, she explained.

In 2005, Sen. Michael Enzi (R-Wyo.) and Sen. Max Baucus (D-Mont.) introduced the Fair and Reliable Medical Justice Act (S. 1337), which would provide money for demonstration projects on alternative methods to address malpractice, including health courts. The Senate Health, Education, Labor, and Pensions Committee held a hearing on the bill in June 2006, but there has been no further action.

At the symposium, Stephen Northrup, the health policy staff director for that committee, said it is not clear whether the newly Democratic-controlled Congress will consider alternatives such as health courts. Because Democrats are unlikely to approve of caps on damages as a tort reform, he said, it is incumbent on physicians to promote alternatives.

The National Committee for Quality Assurance supports the move toward an administrative court, said NCQA general counsel Sharon Donohue. But there is no evidence that rewards will decrease, and with an expanding number of claimants, malpractice premiums might still increase because they are based on the number of claims paid, she said.

Some consumer groups oppose the idea. Linda Kenney, president of the advocacy group Medically Induced Trauma Support Services, said that patients should not be required to start the claims process, as is proposed under the health court system. An audience member representing Consumers Union said that her group did not like the idea of taking away a patient's right to a jury trial.

Dr. Dennis O'Leary, president of the Joint Commission on Accreditation of Healthcare Organizations, also said he saw some basic impediments to using the courts to improve patient safety. Overall, 85% of errors are due to systems issues; only 15% are competency-related, so solutions should focus on systems design, Dr. O'Leary said.

Despite JCAHO's voluntary reporting requirements of the last 10 years, there are few reports of adverse events—maybe 450-500 a year, he said. Most reports concern errors that are not easy to hide, such as patient suicides, which is the top category, and surgical misadventures, the number two category, Dr. O'Leary said. Surprisingly, at least eight cases a month of wrong-site surgery are reported, he added.

Several states have looked at or adopted "I'm sorry" statutes to address malpractice. Under the 2003 law, physicians can apologize, admit fault, and explain the cause of an error without it being held against them in court. The law has reduced the number of cases going to trial in Colorado.

So far, 2,835 of the 6,000 physicians covered by the COPIC Insurance Co., a malpractice insurer, have participated in a program implementing the law, said George Dikeou, a legislative consultant to the company. Participating physicians have had at least 3,200 discussions with patients, and in about 2,000 cases, the discussion was all that was needed to close the case, he said.

The insurer is authorized to pay up to $30,000 per case; the average payout over 711 cases has been about $5,300, Mr. Dikeou said. Of 116 cases that went to court, 54 cases were closed without payment and without attorney involvement. Six cases were closed with payment, 40 are still open, and 16 have gone to trial. ■

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