BY MILES ZAREMSKI, J.D.

LAW & MEDICINE

A Matter of Privilege

Editor's Note: *Welcome to our first installment of Law & Medicine, our new legal column written by Miles Zaremski, J.D., past president of the American College of Legal Medicine. Each month, Mr. Zaremski, who practices in Northbrook, Ill., will discuss an aspect of health law that affects physicians. We welcome your comments on the column; write to us at imnews@elsevier.com.*

The case of *Russell Adkins, M.D. v. Arthur Christie et al.* may not sound very exciting on its face, but it could be a significant one for practicing physicians because of its potential effect on peer review.

Dr. Adkins, an African American, brought suit in federal court against the hospital where he had been practicing, as well as against its administrator and its staff physicians (all located in Georgia) for allegedly discriminating against him by summarily suspending his privileges. Dr. Adkins also alleges his privileges were not renewed because of his race, and that he was not accorded due process.

During discovery, Dr. Adkins sought documents from the hospital's peer review committee relating to peer review of all physicians at the hospital during the 7 years that he was a member of the medical staff. The defendants objected, arguing that the information that Dr. Adkins sought was privileged under Georgia's peer review statute which states: "[T]he proceedings and records of medical review committees shall not be subject to discovery or introduction into evidence in any civil action against a provider of professional health services arising out of the matters which are the subject of evaluation and review by such committee."

Although the federal trial judge found the privilege applicable to federal civil rights actions, he disagreed with what the defendants argued, and ordered them to produce descriptions of events giving rise to peer review without producing the documents themselves.

When the defendants asked that the case be dismissed, the court inspected the documents at issue, but went ahead and dismissed the case. Dr. Adkins appealed to the 11th Circuit Court of Appeals in Atlanta, asserting the trial court improperly recognized the peer review privilege.

The appeals court decided that the privilege protecting peer review documents would not be recognized in Dr. Adkins' civil rights lawsuit, and reversed the decision of the federal court below. After a legal analysis, the court ruled on Oct. 22 that in federal law, privileges such as the one protecting peer review information from disclosure are not favored absent extraordinary circumstances, since privileges can well cloud the truth-seeking process.

In a discrimination case such as this one, protecting peer review information does not trump the right to seek the truth for an asserted violation of a person's—in this case, a physician's—civil rights. At the same time, the U.S. Supreme Court *has* recognized the psychotherapist-patient privilege in one of its own decisions.

The conundrum raised by the 11th Circuit's opinion is not in adding to the "mushiness" of federal decisions addressing when and under what circumstances a peer review privilege should be recognized, but in its failure to recognize how the peer review statute will be applied and interpreted by a state judge considering the very same privilege in light of the same or a quite similar case—for example, civil rights or antitrust cases—that was filed under *state* law.

Regulating health care is state based. Congress has never enacted a federal peer review statute and has never announced its intention to do so.

Moreover, peer review statutes were created to further health care within a particular state by enabling physicians in that state to freely and candidly discuss and review medical care within their institutions and hospitals—thus policing themselves. Consequently, since health care is state based and since regulation of that care is state based, then the interpretation and application of the privilege against disclosure of peer review materials by a federal court should be gleaned from how a state court would use the privilege in the same or similar circumstances.

If the particular state peer review statute does not allow for any disclosure, then a federal court should do the same analysis; if a state court "balances" various factors, for example, to first look at the peer review information before allowing it to be disclosed or limiting the time period when the documents were created, then, likewise, a federal court should arrive at the same result. In the end, health care does not change simply because an aggrieved party, like Dr. Adkins, sues in a federal court, and not in a state court.

After the appeals court ruled against them, the defendants in the *Adkins* case asked the U.S. Supreme Court to take on the case; on January 7, the court said it would not do so. Had it accepted the *Adkins* case, the Supreme Court would have had a real opportunity to instruct its lower federal courts that when confronting the protections afforded by a state peer review statute, they should look to how the state statute is interpreted by the state courts in which the federal court sits. With this approach, there would be uniformity in application by *all* courts throughout both the federal and state systems of jurisprudence.

As it now stands, physicians should continue to note that if they serve on peer review committees, they should be guided by the protections provided in their respective state peer review law. A member of such a committee must realize, however, that the information generated by a peer review committee may well not be privileged from disclosure if the request for information arises from a lawsuit in a federal court. ■

FDA Sets New Conflict-of-Interest Rules for Advisory Panels

BY ALICIA AULT
Associate Editor, Practice Trends

The Food and Drug Administration said it wants to require more public disclosure of advisory committee members' conflicts of interest and the information will be available on a new and improved Web site.

The agency also said it will also post more data in advance of upcoming meetings.

The changes were announced in November in a draft guidance, which does not carry the weight of a rule, but is generally followed by most companies that have products regulated by the FDA. A draft guidance represents the agency's "current thinking on the topic."

According to the FDA, the new emphasis on disclosure is a response to recommendations made by the Institute of Medicine in its 2006 report, "The Future of Drug Safety: Promoting and Protecting the Health of the Public."

The draft guidance will apply to all members of the 31 current advisory panels. Committee members are either government employees or outsiders who are designated as special government employees. The FDA will ask panelists to state publicly the type, nature, and magnitude of any "disqualifying financial interests."

Panel members will be required to complete a waiver request when they have a financial conflict. As part of that document, they'll list the nature of the interest (for instance, whether it's a stock holding, or if they've been a paid consultant or an expert witness); whether the conflicting relationship is with the sponsor or a competitor; and the value of the remuneration, up to $50,000. At least 15 days before an advisory committee meeting, any disclosures from panelists will be posted on the Web site, along with the agency's waiver decision. Currently, waivers may or may not be posted a few days in advance of a committee meeting, and are read aloud at the start of the proceedings.

Critics have charged that panel reviews of products have become less rigorous because so many committee members have conflicts of interest. Essentially, the panels are biased in favor of approval, critics contend.

The National Research Center for Women and Families, a consumer advocacy group, issued a report in 2006 showing that advisory panels backed approval for 76% of new drugs and 82% of new medical devices, and that 96% of those products were later approved by the FDA.

The new guidance "focuses on disclosure, not on change," Diana Zuckerman, Ph.D., president of the National Research Center, said in an interview. "Although disclosure is nice, it doesn't solve the problems."

A recent report that was commissioned by the FDA concluded that creating conflict-free panels would require higher recruiting and screening costs, and would take much more time than the current process, potentially delaying important decisions.

Eastern Research Group, a consulting firm in Lexington, Mass., studied 16 advisory committee meetings that involved 124 panel members. Of the 124, 32 (26%) required waivers for at least one meeting. Almost the same number required waivers for multiple meetings. An equal number of standing members and consumer representatives required waivers (29%). More than half of patient representatives required waivers.

Dr. Zuckerman questioned the study's validity, noting that the consulting company used literature searches to form the basis of its conclusions on panelists' conflicts. The FDA would be more proactive in searching for conflict-free advisers, she said.

She was in favor of the FDA's proposed new voting procedures. The agency said that it wanted to have simultaneous votes. Currently, committees often have panelists vote individually, one by one. That can influence the votes of successive voting members.

Even with this reform, Dr. Zuckerman said she was not satisfied. "I do actually think it's mostly a sham process," she said. "I don't believe that these are independent scientific advisory committees." ■