American Medical News

Supreme Court cases on medical issues rare, but crucial

The average physician might shudder at the thought of a courtroom. But when a case with the potential to impact patient care and medical practice has reached the nation's highest court, doctors historically have seized the opportunity to voice their opinions.

They recently got that chance again when the U.S. Supreme Court in November heard oral arguments in *Wyeth v. Levine* — a case that for many physicians has raised questions about prescription drug access and safety.

In the Courts

By Amy Lynn Sorrel

It is a rare opportunity. The high court accepts only about 1% of petitions filed each term — roughly 75 to 80 cases from 8,000 to 9,000 submitted.

By the time a case lands in the hands of the nine U.S. Supreme Court justices, "the stakes are very, very high," said Theodore B. Olson, a former U.S. solicitor general and now partner at Gibson Dunn & Crutcher LLP in Washington, D.C. "Not only is it rare for the Supreme Court to take a case, but when it does, it invariably involves a very important principle of law," said Olson, who has argued more than 50 cases before the high court, touching everything from *Bush v. Gore* to medical device regulation to the federal False Claims Act.

The Supreme Court typically selects cases involving an interpretation of the U.S. Constitution or federal law, or a conflict among lower courts. At least four of the nine justices must agree a case is important enough to accept review. In *Wyeth,* the court was asked whether federal labeling requirements imposed on pharmaceutical manufacturers by the Food and Drug Administration preempt state lawsuits alleging the companies failed to adequately warn of a drug's risks.

"Once the Supreme Court decides a case, unless Congress comes along and changes the law — which is very unusual — the court is the final word," Olson said.

The attorneys, public participants and media representatives who packed the courtroom the morning of Nov. 3 hung on the justices' every word as they heard oral arguments in *Wyeth*. The case is expected to impact product liability claims involving not just pharmaceuticals, but other federally regulated industries as well.

Trial by fire

Peering down from the raised bench, flanked by two American flags, the black-robed justices took turns grilling the opposing counsel, occasionally flipping through the stacks of case materials at their sides. As the attorneys perched at the lectern, a large golden clock hovering over the bench served as a reminder that each side had just 30 minutes to make its arguments before participants in the next case would be ushered in through the marble columns girding the courtroom.

Despite rapid-fire questioning from Chief Justice John G. Roberts Jr. and Justices Antonin Scalia and Stephen G. Breyer, attorney David C. Frederick said that his role was not "to kowtow to the court. It's to represent a position as firmly and as respectfully as you can. And that means disagreeing with [the justices] when they offer a question or a hypothesis that's incorrect." Frederick represented patient Diana Levine in the case, his 25th before the high court.

But getting this far was no small task. He spent about 200 hours preparing for the event — twice as much time as he typically has spent readying for a Supreme Court battle.

"I formally represented Diana Levine as my client. But in a sense, I also represent every other person out there [in her situation] and felt the weight of that responsibility when preparing," he said.

Levine lost her arm following complications from an IV injection of Wyeth's anti-nausea drug, Phenergan. The company maintains its FDA-approved label contained sufficient warnings about the medication's risks. The FDA had rejected Wyeth's requests for stronger cautions. A Vermont jury found the drug unsafe.

The science involved in *Wyeth* required Frederick to familiarize himself with the drug, as well as FDA regulations and the statutory history behind the process. In addition to rehearsing his arguments in moot court practice runs, he studied 30 friend-of-the-court briefs filed on both sides on

behalf of interested parties including the government, drug industry, consumer advocates and the trial bar.

Doctors' voices reach high court

Those documents also included briefs filed on behalf of several state and national medical societies, and from individual physicians weighing in with different views.

"This is an issue that can significantly affect medical care and it's fully appropriate that doctors were heard," said Eric G. Lasker, a partner with Spriggs & Hollingsworth in Washington, D.C., who specializes in constitutional and pharmaceutical litigation. "The only avenue is through *amicus* briefs … [that] provide the court with a broader perspective and a broader understanding of some of the public policy issues," said Lasker, who authored a joint friend-of-the-court brief in *Wyeth* on behalf of the American College of Emergency Physicians and the Washington Legal Foundation.

The Supreme Court also heard from state medical associations in Texas, North Carolina and California, as well as the *New England Journal of Medicine*.

Wyeth marks the first time the nation's high court will address the scope of prescription drug liability, and is among only a handful of other product liability preemption cases the court has taken in the past 15 years, Lasker noted.

In a February decision, the justices ruled 8-1 in *Riegel v. Medtronic* that patients who are injured by certain FDA-approved medical devices cannot sue the products' manufacturers.

The AMA was not involved in either the *Wyeth* or *Riegel* case.

During the past decade, however, the AMA has participated in more than a dozen Supreme Court cases on a range of issues, including patient privacy, health insurance regulations, tobacco and the death penalty. Organized medicine's involvement came largely in the form of friend-of-the-court briefs filed by the Litigation Center of the American Medical Association and State Medical Societies.

"Patients and physicians are affected every day by legal issues, and the courts have considerable potential to impact the practice of medicine," said AMA Board of Trustees member Cyril M. Hetsko, MD, who serves on the Litigation Center's executive committee. "That's why it's vital we make sure patients' and physicians' point of view is certainly represented in the courtroom."

That goes not just for the nation's highest court, but for all levels of the legal process, he added.

Whether on paper or at the podium, persuading the Supreme Court justices is as much a duty as it is a daunting task, former Solicitor General Olson said.

"The justices are so smart and so well-prepared, you have no room for mistakes," he said. At the same time, "the parties interested in the outcome of the case know it's exceptionally important and do whatever they need to do to win the case." ◆

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Approaching the bench

The AMA, through its Litigation Center, has been involved in cases before the U.S. Supreme Court, including:

***Altria Group v. Good*, pending**

Issue: Whether federal rules on cigarette ads and labeling preempt state laws barring unfair trade practices. Organized medicine filed a brief supporting stronger regulation of tobacco marketing.

Result: Oral arguments heard Oct. 7.

***Ayotte v. Planned Parenthood of Northern New England*, 2006**

Issue: Whether a New Hampshire law requiring parental notification before a minor has an abortion — including in emergencies that could endanger the minor's health — was constitutional. Medicine filed in opposition to the law.

Result: The court found the law unconstitutional because it lacked a health exception. Rather than voiding the entire statute, justices sent it back to the lower courts to be fixed.

***Rush Prudential HMO v. Moran Inc.*, 2002**

Issue: Whether the federal Employee Retirement Income Security Act superseded an Illinois HMO law allowing independent review of medical necessity. Medicine filed in support of the state law.

Result: The high court said the state law was a permissible insurance regulation.

***City of Charleston v. Ferguson*, 2001**

Issue: Whether mandatory drug testing of pregnant women seeking OB care at a state-funded hospital was constitutional. Medicine filed in opposition to the mandate.

Result: The court said the policy violated the 4th Amendment prohibition on unwarranted searches and seizures.