

Legal Notes

DR. KYL SMITH FILES PHOSPHATIDYLSERINE HEALTH CLAIM PETITION WITH THE FDA

Kyl Smith, D.C., filed a health claim petition with the Food and Drug Administration today asking the agency to approve the following two health claims for use on labels and in labeling of dietary supplements that contain phosphatidylserine:

The consumption of phosphatidylserine may reduce the risk of cognitive dysfunction in the elderly.

The consumption of phosphatidylserine may reduce the risk of dementia in the elderly.

This is the first time a party has filed a health claim petition for reduction in the risk of diseases of the brain.

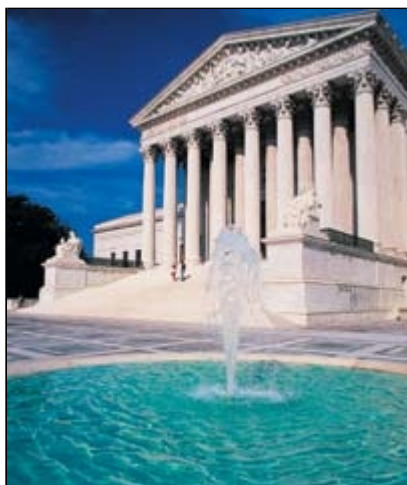
Dr. Smith's petition is supported by a substantial amount of scientific evidence on the role of phosphatidylserine, a compound commonly found in the healthy human brain that can be isolated from soya and egg yolks among other food sources. The petition is accompanied by a scientific report from Michael John Glade, Ph.D., F.A.C.N., C.N.S., former Senior Scientist of the American Medical Association.

FDA has 540 days within which to act on the petition. Dr. Smith has asked the FDA to approve the petition under its health claims review standard or, if FDA chooses not to approve the petition, to allow use of the claims with disclaimers as required by the United States Court of Appeals' *Pearson v. Shalala* decision.



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SUPREME COURT ROUNDUP



On April 30, 2002, declaring that "regulating speech must be a last-not first-resort," the Supreme Court invalidated a provision of the federal food and drug laws that banned pharmacies from advertising the availability of "compounded" pharmaceuticals, drugs that pharmacists make themselves by mixing ingredients to meet the specific medical needs of certain patients.

A 1997 federal law that barred such advertising reflected federal regulators' concern that compounded drugs did not go through the detailed screening for safety and effectiveness to which drug companies have to submit their mass-produced drugs. In Congress' view, the advertising ban would limit consumer demand for compounded drugs.

But the 5-to-4 decision on April 30th said that "the government simply has not provided sufficient justification here" for choosing a restriction on speech rather than other possible ways to restrict access to compounded drugs, which generally are not commercially available and which patients may receive only by a doctor's prescription.

"We have made clear that if the government could achieve its interests in a manner that does not restrict speech, or that restricts less speech, the government must do so," Justice Sandra Day O'Connor said for the majority.

In a dissenting opinion, Justice Stephen G. Breyer characterized the decision as an "oversimplification" of a complex regulatory issue that "gives insufficient weight to the government's regulatory rationale, and too readily assumes the existence of practical alternatives."

The real debate on the court was not over drug policy but over the constitutional value to assign to commercial speech. While the majority opinion today did not break ground, it was a powerful indication that the value a majority of the court assigns to commercial speech is high and getting higher.

The majority opinion was joined by Justices Antonin Scalia, Anthony M. Kennedy, David H. Souter and Clarence Thomas. Chief Justice William H. Rehnquist joined Justice Breyer's dissenting opinion, as did Justices John Paul Stevens and Ruth Bader Ginsburg.

The decision, *Thompson v. Western States Medical Center*, No. 01-344, affirmed a ruling last year by the United States Court of Appeals for the Ninth Circuit, in San Francisco. Eight licensed pharmacies, each of which specializes in compounding particular types of drugs, sued in Federal District Court in Las Vegas to overturn the advertising ban. They were supported in the Supreme Court by several pharmacy trade associations.

Justice O'Connor's majority opinion adopted a scolding tone toward the government's defense of the statute, and by implication toward Congress, reflecting the disdain the court has expressed with increasing frequency toward the legislative process.

The opinion outlined alternatives that, in the court's view, Congress should have used before turning to an advertising ban, most dealing with limitations on the amount of compounded drugs an individual pharmacy could make or sell. Or the government could require warning labels advising consumers that the compounded drug had not gone through the usual approval process, Justice O'Connor said.

"The government has not offered any reason why these possibilities, alone or in combination, would be insufficient to prevent compounding from occurring on such a scale as to undermine the new drug approval process," she said, adding, "Indeed, there is no hint that the government even considered these or any other alternatives."

She continued: "If the First Amendment means anything, it means that regulating speech must be a last-not first-resort. Yet here it seems to have been the first strategy the government thought to try."

In the dissenting opinion, Justice Breyer said the court was interpreting the First Amendment to give too much protection to commercial speech and too little attention to "the importance of the government's interest in protecting the health and safety of the American public."

The court's proposed alternatives were not likely to be effective, Justice Breyer said, adding, "An overly rigid commercial speech doctrine will transform what ought to be a legislative or regulatory decision about the best way to protect the health and safety of the American public into a constitutional decision prohibiting the legislature from enacting necessary protections."

The legal status of compounded drugs after the decision today was not immediately clear. The government took the position that such drugs were not legal before the 1997 law, the Food and Drug Administration Modernization Act, which made their lawful sale contingent on the advertising ban and on other restrictions. The Ninth Circuit, holding that the various provisions of the law could not be considered separately, struck down the entire statute, an aspect of its ruling that the court did not address on April 30th.

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