

Care Pharmacy, Pet Health Pharmacy Inc., Plum Creek Pharmaceuticals, Inc., Premier Pharmacy, University Compounding Pharmacy, Veterinary Pharmacies of America, and Women's International Pharmacy, Inc. ("Plaintiffs").

Statement of the Interest of *Amicus Curiae*

Founded in 1943, the Association is a nationwide non-profit membership organization of thousands of physicians, incorporated under the laws of Indiana. Members of the Association have been responsible for treating millions of patients. Association members recognize that compounding pharmacies play an essential role in filling prescriptions for medication not otherwise available. Members of the Association need continued access to compounding pharmacies without undue interference by the federal government.

The Association seeks to file an *amicus curiae* brief here to ensure the continued vitality of compounding pharmacies as regulated by the States rather than by the federal government. The Association has an immediate interest in protecting and preserving the ability of physicians to continue utilizing compounding pharmacies.

This Court granted the Association's prior motion for leave to file an *amicus curiae* brief in opposition to Defendants' Motion to Dismiss on March 22, 2005. There, as there, the Association brings the views of an independent group of physicians to the litigation of medical issues, for the benefit of this Court.¹

¹ The Association informed counsel for defendants, Gerald Kell, of the arguments being raised by the Association and requested his consent to this motion. He declined consent.

ARGUMENTS TO BE PRESENTED BY THE *AMICUS CURIAE*

Amicus Association seeks to alert this Court to three arguments that are dispositive of this case and which require granting summary judgment in favor of Plaintiffs, as outlined below.

1. States, not the federal government, regulate the practice of medicine. This was reiterated again by the Supreme Court this year in *Gonzales v. Oregon*, and its logic requires judgment in favor of Plaintiffs here. That decision concerned a federal “Interpretive Rule” (analogous to the Compliance Policy Guide at issue here) governing end-of-life drugs, and the Supreme Court struck down the federal rule. “The Government, in the end, maintains that the prescription requirement delegates to a single executive officer the power to effect a radical shift of authority from the States to the Federal Government to define general standards of medical practice in every locality. **The text and structure of the [federal law] show that Congress did not have this far-reaching intent to alter the federal-state balance and the congressional role in maintaining it.**” *Gonzales v. Oregon*, ___ U.S. ___; 126 S. Ct. 904, 925; 163 L. Ed. 2d 748, 778 (2006) (emphasis added). Likewise, Congress never altered the federal-state balance towards compounding pharmacies in the manner sought by the federal government here. Compounding pharmacies are fully legal and the federal government’s authority over them is sharply limited by statute.

2. Compounded drugs are not “new drugs” subject to approval by the United States Food and Drug Administration (FDA) any more than off-label use of drugs for children are. A federal court properly invalidated the FDA’s Pediatric Rule to require testing of new drugs in children, and by analogy the FDA cannot re-categorize compounded drugs as “new drugs” either. *Ass’n of Am., Physicians & Surgeons, Inc. v. United States FDA*, 226 F. Supp. 2d 204, 222 (D.D.C. 2002) (“This court does not pass judgment on the merits of the FDA’s regulatory scheme. The Pediatric Rule may well be a better policy tool than the one enacted by Congress; it might reflect the most thoughtful, reasoned, balanced solution to a vexing public health problem. **The issue here is not the Rule’s wisdom. Indeed, if that were the issue, this court would be a poor arbiter indeed. The issue is the Rule’s statutory authority, and it is this that the court finds lacking.**”) (emphasis added).

3. The action and inaction of Congress confirm its view that compounding pharmacies are fully legal and vital to our health care system. In 1999, United States Senator Kit Bond, now serving his fourth term, had the following exchange with Senator Thad Cochran, who is now serving his fifth term:

Mr. BOND. ... Pharmacy compounding is a part of the practice of pharmacy that involves specially-tailoring a prescription drug product for a specific patient's needs. A good example is when a pharmacist takes a pill prescribed for an infant--but which that infant can't swallow--and grinds it up and mixes it into a sweet syrup that the baby is happy to take. **Pharmacy compounding has been part of what pharmacists do for centuries, and it is important to preserve their ability**

to do this without huge regulatory hassles. Pharmacy compounding is important for many patients who need specially-designed drugs because no commercially-available product meets their specific needs. Interfering with compounding will only hurt these patients by making it more difficult to get--or even denying them--the specific pharmaceutical products they need. ...

Mr. COCHRAN. I thank my colleague from Missouri for raising this issue. **For patients who have very specific pharmaceutical needs, pharmacy compounding is clearly extremely important, and I don't believe the federal government should be creating unnecessary hassles or problems for pharmacists who are legitimately serving these patients needs.**

145 Cong Rec S 7295, 7309 (June 21, 1999) (emphasis added).

United States Senator Edward Kennedy, serving his eighth term, is reportedly preparing legislation to grant the federal government powers over compounding pharmacies like what it seeks in this litigation. “Sen. Edward Kennedy (D-Mass.) is preparing legislation that would place greater controls on drug compounding, a practice in which pharmacists manufacture prescription drugs from bulk ingredients, according to a source close to the legislative discussions. ... A Kennedy spokeswoman confirmed the senator is looking into legislation to prevent illegal and inappropriate compounding.” “Kennedy Considering Legislation to Expand Controls on Drug Compounding,” 5 Drug Industry Daily No. 44 (Mar. 3, 2006). But the FDA can only obtain such powers through legislation. Maybe Senator Kennedy will sponsor legislation to grant the FDA the powers it wants, and maybe such legislation will pass over the objections of Senators Bond and Cochran. But the FDA lacks those powers unless and until

Congress affirmatively grants them and the President signs the bill into law, or his veto is overridden. The FDA cannot simply take by fiat what Congress has not granted.

CONCLUSION

Amicus Association respectfully asks the Court to grant leave to file its *amicus curiae* brief in support of Plaintiffs.

Respectfully submitted,

**ATTORNEY FOR *AMICUS CURIAE* ASSOCIATION
OF AMERICAN PHYSICIANS AND SURGEONS, INC.**

By: _____
Karen Tripp, Esq.
Texas State Bar No. 03420850
2245 Shakespeare Rd.
Houston, TX 77030
(713) 658-9323
(713) 658-9410 (fax)
Counsel for *Amicus Curiae*

April 7, 2006

CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing instrument has been forwarded to all counsel of record herein by way of electronic mail and by overnight delivery on this 7th day of April, 2006, to:

HANCE SCARBOROUGH WRIGHT WOODWARD & WEISBART
111 Congress Avenue, Suite 500
Austin, Texas 78701
(512) 479-8888
(512) 482-6891 (facsimile)
Attorneys for Plaintiffs

Gerald C. Kell
OFFICE OF CONSUMER LITIGATION
1331 Pennsylvania Avenue N.W., Suite 950-N
Washington, D.C. 20004
(202) 514-1586
(202) 514-8742 (facsimile)
Attorney for Defendant

Karen Tripp