



Pharmaceuticals, Inc., Premier Pharmacy, University Compounding Pharmacy, Veterinary Pharmacies of America, and Women's International Pharmacy, Inc. ("Plaintiffs").<sup>1</sup>

## **I. 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 submits this *amicus curiae* brief 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.

The Association brings the views of an independent group of physicians to the litigation of medical issues, for the benefit of this Court.

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<sup>1</sup> This Court granted leave for submission of this *amicus curiae* brief by its Order dated April 24, 2006.

## ARGUMENTS

This Court should enter summary judgment against the Acting Commissioner of the United States Food and Drug Administration (“FDA”) and his co-defendants for three independent reasons. First, the recent Supreme Court decision of *Gonzales v. Oregon*, 126 S. Ct. 904, 163 L. Ed. 2d 748 (2006), requires summary judgment for Plaintiffs. Second, a federal district court has already ruled against the FDA in its very similar attempt to expand its power over new drugs with respect to use by children. Third, the statements and actions of congressmen confirm that States, not the federal government, regulate compounding pharmacies.

### **A. The Recent Supreme Court Decision of *Gonzales v. Oregon* Requires Judgment in Favor of Plaintiffs.**

The expansion in regulatory power sought by the FDA here is indistinguishable from the federal overreaching rejected by the Supreme Court in *Gonzales v. Oregon*. Its issue 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. For the same reasons articulated in that decision, this Court should hold against the FDA here.

States, not the federal government, regulate the practice of medicine. “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*, 126 S. Ct. 904, 925, 163 L. Ed. 2d 748, 778 (2006). 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 regulated by the States, not by the federal government in the sweeping manner it proposes.

In *Gonzales*, there was even a stronger governmental interest in regulating the prescriptions than there is here. *Gonzales* concerned the authority of the federal government to regulate controlled substances, having undeniable danger to the public, pursuant to authority granted by Congress. The Schedule II controlled substances at issue in *Gonzales* pose a far greater risk of harm to the public than the compounded drugs implicated by this action. But the federal-state balance remains the same in both cases: the power over compounding pharmacies resides with the States, not with the federal government.

Already the Court of Appeals for the Fifth Circuit has expressly embraced the teaching in *Gonzales* in the jurisdictional context. The Fifth Circuit noted that *Gonzales* echoed the principle that “[w]here Congress aims to change the usual constitutional balance between the states and the federal government, **it must**

**make unmistakably clear its intention to do so in the statute’s language.”**

*Premiere Network Servs. v. SBC Comm.*, 440 F.3d 683, 690 n.8 (5<sup>th</sup> Cir. 2006) (citing *Will v. Michigan Dep’t of State Police*, 491 U.S. 58, 65 (1989) and *Gonzales v. Oregon, supra*, emphasis added).

There is no “unmistakably clear” intention in federal law to authorize the FDA to regulate compounding pharmacies, which have always been regulated by the States, in the expansive manner sought by the FDA. The FDA’s arguments in its motion for summary judgment simply ignore and would disrupt the delicate federal-state balance in a manner analogous to what the Supreme Court emphatically rejected in *Gonzales v. Oregon*. Congress certainly knows how transfer, if it so desired, regulatory power over compounding pharmacies from the States to the federal government. But Congress has plainly not done so.

The FDA should be restrained here from upsetting the “constitutional balance between the states and the federal government.” *Premiere Network Servs. v. SBC Comm.*, quoted *supra*. Accordingly, the FDA should be enjoined from requiring inspections of the business records of compounding pharmacies operating in compliance with State law, and enjoined from asserting that compounded drugs are new drugs subject to the FDA’s approval process.

**B. Compounded Drugs Are Not “New Drugs” Subject to Approval by the FDA.**

Compounded drugs are not “new drugs” subject to approval by the FDA any more than untested, off-label prescriptions of drugs for children are. A federal court properly invalidated an attempt by the FDA, analogous to its attempt here, to impose new testing requirements in order to ensure safety for off-label use of drugs by children (the “Pediatric Rule”). In holding against the FDA, the federal court adopted reasoning that applies with equal force against the FDA’s arguments here. *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).

The dispute in that case concerned how drugs are often prescribed for children in a manner never tested or approved by the FDA. Those “off-label” uses are not contemplated by the labeling on the drugs or its approval for use by the FDA. Off-label prescriptions are pervasive and unregulated by the FDA, yet completely legal. They are conceptually similar to compounded drugs, whereby

the physician makes a determination that a usage never approved by the FDA is in the best interests of the patient. The FDA sought authority over off-label prescriptions in order to protect the safety of children, but the court properly struck down the FDA's rule. "When an agency's assertion of power into new arenas is under attack, therefore, courts should perform a close and searching analysis of congressional intent ...." *Id.* at 212 (quoting *ACLU v. FCC*, 823 F.2d 1554, 1567 n.32 (D.C. Cir. 1987)). There, as here, congressional intent was to respect the traditional practice of medicine by physicians, which has allowed off-label prescriptions. *See, e.g., Ass'n of Am. Physicians & Surgeons v. FDA*, 226 F. Supp. 2d 204, 215 ("[T]raditionally, the FDA has required manufacturers to test products only for the product's labeled use."). Similarly, the traditional practice of medicine has permitted the use of compounded drugs without FDA interference.

This Court should reach the same conclusion about the FDA's attempt to regulate compounded drugs as the *Ass'n of Am. Physicians & Surgeons v. FDA* court did in rejecting the FDA's attempt to regulate drugs with respect to off-label prescriptions for children. "[T]he Pediatric Rule exceeds the FDA's statutory authority and is therefore invalid." *Id.* at 222.

### **C. Congressional Action and Statements Confirm the Legal and Vital Role of Compounding Pharmacies.**

The action and inaction of Congress confirm its view that compounding pharmacies are fully legal and vital to our health care system. In 1999, two senior members of the United States Senate declared their understanding of the essential role played by compounded pharmacies. The Congressional Record captured this exchange between United States Senator Kit Bond, now serving his fourth term, and Senator Thad Cochran, 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. S7295, S7309 (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). This effort underscores how the FDA needs new legislation to obtain the powers it seeks. Maybe Senator Kennedy will sponsor legislation to grant the FDA its desired powers, and perhaps such legislation can even pass over the objections of Senators Bond and Cochran. But the FDA lacks such 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. “[I]t seems highly unlikely that a responsible Congress would implicitly delegate to an agency the power to define the scope of its own power.” *Ass’n of Am. Physicians & Surgeons v. FDA*, 226 F. Supp. 2d at 212 (quoting *ACLU v. FCC*, 823 F.2d at 1567 n.32).

The government should be enjoined here from exercising powers that Congress has not yet, and may never, grant to it.

**CONCLUSION**

For all the foregoing reasons, *amicus* Association respectfully asks this Court to grant Plaintiffs' motion for summary judgment.

Respectfully submitted,

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Dated:        May 9, 2006

## **CERTIFICATE OF SERVICE**

I hereby certify that a true and correct copy of the foregoing document has been forwarded to all counsel of record herein by way of electronic mail and by overnight delivery on this 9<sup>th</sup> day of May, 2006, to:

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