Docket No. 06-51583
IN THE UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT

MEDICAL CENTER PHARMACY, APPLIED PHARMACY, COLLEGE PHARMACY, MED SHOP TOTAL CARE PHARMACY, PET HEALTH PHARMACY INCORPORATED, PLUM CREEK PHARMACEUTICALS INCORPORATED, PREMIER PHARMACY, UNIVERSITY COMPOUNDING PHARMACY, VETERINARY PHARMACIES OF AMERICA, and WOMEN'S INTERNATIONAL PHARMACY, INCORPORATED,

Plaintiffs-Appellees,

v.

ALBERTO GONZALES, in his official capacity as ATTORNEY GENERAL, UNITED STATES, DEPARTMENT OF JUSTICE, MICHAEL O. LEAVITT, in his official capacity as SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES, and ANDREW C. VON ESCHENBACH, in his official capacity as the ACTING COMMISSIONER of the UNITED STATES FOOD AND DRUG ADMINISTRATION,

Defendants-Appellants.

On Appeal From The United States District Court
For The Western District Of Texas, Midland-Odessa Division

BRIEF FOR *AMICUS CURIAE* THE ASSOCIATION OF AMERICAN PHYSICIANS AND SURGEONS, INC. FILED IN SUPPORT OF PLAINTIFFS-APPELLEES IN SUPPORT OF THE JUDGMENT BELOW

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CERTIFICATE OF INTERESTED PERSONS

Pursuant to Fifth Circuit Local Rule 28.2.1, the undersigned counsel for *Amicus Curiae* The Association of American Physicians and Surgeons, Inc. incorporates by reference the certificate of interested persons by Plaintiffs-Appellees and certifies the following supplemental information concerning the outcome of this appeal, No. 06-51583:

1. The *Amicus Curiae* Association of American Physicians and Surgeons, Inc. is a nonprofit corporate party that lacks any parent corporation.

2. The *Amicus Curiae* Association of American Physicians and Surgeons, Inc., a membership organization, does not have stock. There is no publicly held corporation that owns 10% or more of any stock in the Association of American Physicians and Surgeons, Inc.

3. The *Amicus Curiae* Association of American Physicians and Surgeons, Inc., as a legal entity separate from its members, does not have a financial interest in the outcome of this litigation.

Dated: June 6, 2007

_____

Andrew L. Schlafly
Attorney for The Association of American Physicians and Surgeons, Inc.

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STATEMENT OF IDENTITY, INTEREST AND SOURCE OF AUTHORITY TO FILE

The Association of American Physicians and Surgeons, Inc. (the "Association") is a non-profit national organization consisting of thousands of physicians in all specialties. Founded in 1943, the Association is incorporated under the laws of Indiana. Members of the Association have been responsible for treating millions of patients. Association members rely on compounding pharmacies to provide medication for patients not otherwise available. As practicing physicians, members of the Association need continued access to compounding pharmacies without undue interference by the federal government. The Association brings the views of an independent group of physicians to the litigation of medical issues, for the benefit of this Court.

The Association submits this *amicus curiae* brief to ensure the continued vitality of compounding pharmacies as properly 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 has filed *amicus* briefs in cases of high importance to the medical profession. *See, e.g.*, *Stenberg v. Carhart*, 530 U.S. 914 (2000) (the U.S. Supreme Court citing the Association's submission); *Springer v.*

Henry, 435 F.3d 268, 271 (3d Cir. 2006) (citing the Association's *amicus* brief in the first paragraph of the opinion).

All parties to this litigation consent to the filing of this *amicus curiae* brief by the Association in support of the Plaintiffs-Appellees.

ARGUMENT

This case concerns an attempt by the United States Food and Drug Administration ("FDA") to expand its authority into a field traditionally regulated by the States – compounding pharmacies – without a clear mandate by Congress. The court below properly rejected this attempt under the Federal Food, Drug, and Cosmetic Act (the "FDCA"), 21 U.S.C. § 301, *et seq*. The delicate balance between federal and state power cannot be altered unless Congress is unmistakably clear. Congress has exhibited no such intent under the FDCA or any other statute. The FDA cannot, and does not, make the requisite showing to justify the expansion in federal power that it seeks. The decision below should be affirmed.

The FDA's attempt to expand its power is as unwise as it is legally unjustified. It is essential to patient care for physicians to have the continued ability to write prescriptions for compounded drugs, and have them filled by a local compounding pharmacy, under the traditional regulatory authority of

state governments. This local control has worked, and worked well, for centuries. The FDA has no more justification for declaring compounded drugs to be "new drugs" subject to its authority than the U.S. Department of Education would have in seizing full regulatory control of all schools, public and private. Compounding pharmacies are regulated at the state level; legal and policy considerations support keeping the control at that local level.

The decision below never reached the issue of federalism, but this Court may affirm the decision on any grounds supported by the record. *See Teague v. Quarterman*, 482 F.3d 769, 773 (5th Cir. 2007) ("We may affirm a district court's decision on any basis established by the record."); *Ballard v. Burton*, 444 F.3d 391, 401-02 (5th Cir. 2006) ("Even though we have concluded that the reasons given by the district court do not support the summary judgment entered against Ballard, we may affirm this judgment on any other grounds supported by the record."); *Davis v. Scott*, 157 F.3d 1003, 1005 (5th Cir. 1998) ("[T]his court may affirm a judgment upon any basis supported by the record."). As explained below, there is ample basis for affirming the judgment by the district court.

I. The Applicable *Chevron* Rule, Misstated by the Government Here, Requires Affirmance for Lack of an "Unmistakably Clear" Mandate by Congress to Alter Traditional State Regulation of Compounding Pharmacies.

Where federalism is at stake, the applicable *Chevron* rule is that Congress must be "unmistakably clear" about injecting federal power into any traditionally state-held jurisdiction. Federalism is at stake here as the FDA seeks to expand its authority over compounding pharmacies, which have traditionally been regulated by the States. The requisite congressional clarity is lacking for an intrusion into this state domain by the FDA in declaring compounded drugs to be subject to its new drug approval process.

Precisely stated, *Chevron* allows for deference to the agency interpretation only if the governing law is ambiguous *under canons of statutory construction*. "If a court, **employing traditional tools of statutory construction**, ascertains that Congress had an intention on the precise question at issue, that intention is the law and must be given effect." *Chevron U.S.A. Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837, 843 n.9 (1984) (emphasis added). Where, as here, the dispute concerns "the usual constitutional balance between the states and the federal government," then statutory construction requires that Congress "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 (5th Cir. 2006) (citing *Will v. Michigan*

Dep't of State Police, 491 U.S. 58, 65 (1989) and *Gonzales v. Oregon*, 546 U.S. 243 (2006), emphasis added).

The Government bases its appeal here on its misstatement of the governing standard. It errs in arguing that this court should "defer[] to FDA's interpretation of the FDCA" if "'Congress has not directly addressed the precise question at issue.'" Govt. Br. at 22 (quoting *Chevron*, 467 U.S. at 843). No deference to the FDA's interpretation is appropriate here because the rules of statutory construction require Congress to be "unmistakably clear." In this context, lack of complete clarity in the statute ends the judicial inquiry. Ambiguity cannot be a basis for altering the "usual constitutional balance" of state regulation of compounding pharmacies in favor of FDA control.

A. The Government Errs in Asserting Deference for the Agency Interpretation, as *Gonzales v. Oregon* Already Rejected This Argument for Deference.

The Government errs in declaring the standard of review to require deference to the FDA's interpretation in defining the scope of its own power. Specifically, the Government argues that the FDA's assertion of power here should be reversed "only if it is 'arbitrary, capricious, or manifestly contrary to the statute.'" Govt. Br. at 23 (quoting *Texas Coal. Of Cities for Util. Issues v. FCC*, 324 F.3d 802, 807 (5th Cir. 2003)). But interpretations by agencies are not entitled to any deference in expanding into state jurisdiction, and the

Supreme Court has acknowledged that the regulation of compounding pharmacies has traditionally been done by the States. *Thompson v. Western States Med. Ctr.*, 535 U.S. 357, 362 (2002). An "unmistakably clear" mandate from Congress itself is necessary, and it is lacking in the case at bar.

The Supreme Court emphatically rejected the Government's argument of deference to an agency position on an issue relating to the federal-state balance in *Gonzales v. Oregon*, 546 U.S. 243 (2006). The Government's brief does not, and cannot, distinguish that opinion despite its similarity to the principle at stake here. There, another governmental agency, the Department of Justice, sought to expand federal power into the state regulation of physician-assisted suicide. The Court rejected the argument that *Chevron* deference should apply to an agency attempt to reallocate the federal-state balance:

> 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.

546 U.S. at 275. *See also id.* at 272 ("[W]hen Congress wants to regulate medical practice in the given scheme, it does so by explicit statutory language").

The expansion in regulatory power sought by the FDA here is akin to the federal overreaching rejected by the Supreme Court in *Gonzales v. Oregon*. There the 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 affirm the decision 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*, 546 U.S. at 275. 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 an even 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* are highly regulated by the federal government pursuant to statutory authority because they have a high potential for abuse. Those drugs pose a far greater risk of harm to the public than the compounded drugs implicated by this action. But the federal-state balance is similar in both cases: the power over compounding pharmacies resides with the States, not with the federal government. Only Congress and not an agency, and only Congress acting with complete statutory clarity, can alter that balance of power by declaring compounded drugs to be new drugs subject to FDA approval. The decision below should be affirmed.

B. This Court and Numerous Precedents Militate Against Altering the Balance Between the State and Federal Governments Unless Congress Was "Unmistakably Clear," and It Was Not.

This Circuit has emphasized 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 (5th Cir. 2006) (citing *Will v. Michigan Dep't of State Police*, 491 U.S. at 65, and *Gonzales v. Oregon*, *supra*, emphasis added). This reflects a long line of Supreme Court authority.

In *Raygor v. Regents of the Univ. of Minn.*, 534 U.S. 533 (2002), the Court interpreted a federal statute in order to avoid intruding on state sovereignty in the absence of a clear statement by Congress. Justice Sandra Day O'Connor cited many precedents for this rule of law:

> When "Congress intends to alter the 'usual constitutional balance between the States and the Federal Government,' it must make its intention to do so 'unmistakably clear in the language of the statute.'" *Will v. Michigan Dep't of State Police*, 491 U.S. 58, 65, 105 L. Ed. 2d 45, 109 S. Ct. 2304 (1989) (quoting *Atascadero State Hosp. v. Scanlon*, 473 U.S. 234, 242 (1985)). This principle applies when Congress "intends to pre-empt the historic powers of the States" or when it legislates in "'traditionally sensitive areas'" that "'affect the federal balance.'" *Will*, *supra*, at 65 (quoting *United States v. Bass*, 404 U.S. 336, 349, 30 L. Ed. 2d 488, 92 S. Ct. 515 (1971)). In such cases, the clear statement principle reflects "an acknowledgment that the States retain substantial sovereign powers under our constitutional scheme,

> powers with which Congress does not readily interfere." *Gregory v. Ashcroft*, 501 U.S. 452, 461, 464, 115 L. Ed. 2d 410, 111 S. Ct. 2395 (1991).

534 U.S at 543-44. Justice Ginsburg agreed with the above restatement of the law and even called it "pivotal". 534 U.S. at 548 (Ginsburg, J., concurring).

The case at bar is conceptually similar to the attempt by the Federal Trade Commission (FTC) to regulate the legal profession under *Chevron* deference. *ABA v. FTC*, 430 F.3d 457 (D.C. Cir. 2005). There, as here, a federal agency sought to expand its authority by claiming that it was entitled to deference in its interpretation of the governing statute. The D.C. Circuit emphatically rejected that argument. "It is undisputed that the regulation of the practice of law is traditionally the province of the states. Federal law 'may not be interpreted to reach into areas of State sovereignty unless the language of the federal law compels the intrusion.'" 430 F.3d at 471 (quoting *City of Abilene v. FCC*, 164 F.3d 49, 52 (D.C. Cir. 1999)). The Court concluded:

> The states have regulated the practice of law throughout the history of the country; the federal government has not. This is not to conclude that the federal government could not do so. We simply conclude that it is not reasonable for an agency to decide that Congress has chosen such a course of action in language that is, even charitably viewed, at most ambiguous.

430 F.3d at 472. The same can and should be said about compounding pharmacies here.

The Court in *ABA v. FTC* then made this colorful observation in thoroughly rejecting the agency's argument for deference in statutory interpretation, an observation apt here as well:

> To find this [agency] interpretation deference-worthy, we would have to conclude that Congress not only had hidden a rather large elephant in a rather obscure mousehole, but had buried the ambiguity in which the pachyderm lurks beneath an incredibly deep mound of specificity, none of which bears the footprints of the beast or any indication that Congress even suspected its presence. We therefore seriously doubt that Congress intended to empower the Commission to undertake that regulation, and we are reluctant to even afford the regulation the deference due agency action that survives the analysis at the first step of *Chevron*.

430 F.3d at 469 (citing *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 160-61 (2000)).

Here the FDA seeks to displace the traditional state authority over compounding pharmacies. Its approach would "alter the 'usual constitutional balance between the States and the Federal Government.'" *Gregory v. Ashcroft*, 501 U.S. 452, 460 (1991) (quoting *Atascadero State Hosp.*, 473 U.S. at 242). But "it is incumbent upon the federal courts to be certain of Congress' intent" before infringing on the state regulation of medicine. *Id.* (quotation marks and citation omitted). *See also United States v. Lopez*, 514 U.S. 549, 576 (1995) (Kennedy, J., concurring) ("federalism was the unique contribution of the Framers to political science and political theory. Though on the surface the idea may seem counter-intuitive, it was the insight of the

Framers that freedom was enhanced by the creation of two governments, not one.") (citing Henry Friendly, *Federalism: A Foreword*, 86 Yale L. J. 1019 (1977) and Gordon Wood, *The Creation of the American Republic, 1776-1787*, at 524-532, 564 (1969)); *United States v. Bass*, 404 U.S. 336, 349 (1971) ("Unless Congress conveys its purpose clearly, it will not be deemed to have significantly changed the federal-state balance."); *Linder v. United States*, 268 U.S. 5, 18 (1925) ("Obviously, direct control of medical practice in the States is beyond the power of the Federal Government.").

The Government's brief fails to argue that Congress was "unmistakably clear" in granting authority to the FDA to expand into the state regulation of compounding pharmacies. Such argument would be without basis in the statute. The thrust of the Government's brief is that the applicable law is ambiguous, and that under *Chevron* the FDA can use that ambiguity to expand its authority. "In refusing to defer to FDA's interpretation of the FDCA, the court committed reversible error," the Government concludes. Govt. Br. at 39. But as shown above, to the extent the law is ambiguous, it fails the threshold requirement that it be "unmistakably clear" in order to expand FDA authority into the traditional domain of regulation by the States. The bulk of the Government's appeal therefore fails by its own admission of ambiguity.

Finally, there is a logical circularity in the Government's argument that an agency can define the scope of its own authority. This circular argument has been rejected elsewhere. "'[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. United States FDA*, 226 F. Supp. 2d 204, 212 (D.D.C. 2002) (quoting *ACLU v. FCC*, 823 F.2d 1554, 1567 n.32 (D.C. Cir. 1987)).

The FDA cannot redefine its own authority to extend broadly to compounded drugs. The decision below should be affirmed.

II. The Decision Below Correctly Cited Public Policy as an Additional Reason to Deny Expanding Authority for the FDA.

The district court properly found additional support for its decision in a compelling public policy rationale:

> Finally, public policy supports exempting compounded drugs from the new drug definitions. If compounded drugs were required to undergo the new drug approval process, the result would be that patients needing individually tailored prescriptions would not be able to receive the necessary medication due to the cost and time associated with obtaining approval. When a licensed practitioner writes a prescription for a compounded drug for a patient, the medication is normally needed soon thereafter. It is not feasible, either economically or time-wise, for the needed medications to be subjected to the FDA approval process. **It is in the best interest of public health to recognize an exemption for compounded drugs that are created based on a prescription written for an individual patient by a licensed practitioner.**

Medical Ctr. Pharm. v. Gonzales, 451 F. Supp. 2d 854, 864-65 (W.D. Tex. 2006) (emphasis added).

The above observation by the lower court is in full accord with the teaching of the U.S. Supreme Court that "Pharmacists do not make enough money from small-scale compounding to make safety and efficacy testing of their compounded drugs economically feasible, so requiring such testing would force pharmacists to stop providing compounded drugs." *Western States*, 535 U.S. at 369-70. In other words, it is economic nonsense to subject compounded drugs to the "new drug" approval process. One can hardly infer that Congress intended to mandate what is economically absurd.

The U.S. Supreme Court recently cited public policy in an analogous manner to reject an interpretation by the Government of an environmental statute in *Rapanos v. United States***,** 126 S. Ct. 2208 (2006). The Court wrote:

> Whether the benefits of particular conservation measures outweigh their costs is a classic question of public policy that should not be answered by appointed judges. **Neither, however, should it be answered by appointed officers of the Corps of Engineers in contradiction of congressional direction.** It is the dissent's opinion, and not ours, which appeals not to a reasonable interpretation of enacted text, but to the great environmental benefits that a patently unreasonable interpretation can achieve. We have begun our discussion by mentioning, to be sure, the high costs imposed by that interpretation -- but they are in no way the basis for our decision, which rests, plainly and simply, upon the limited meaning that can be borne by the phrase "waters of the United States."

Id. at 2233 (emphasis added, quotation marks omitted).

A. The FDA Has Failed in Exercising Approval Authority Over Generic Drugs, Demonstrating that It Would Also Fail in Regulating Compounded Drugs.

It would be a tragic mistake to submit compounded drugs to the FDA approval process, in light of its failure to approve generic drugs. There would be harmful consequences throughout medical practice if physicians were limited in their ability to prescribe compounded medication based on what the FDA deemed acceptable.

The Government insists here that "it is not the function of the courts to make public policy," Govt. Br. at 44, but then proceeds to rely heavily on its own public policy argument in the hope of persuading this Court. The Government insists here that the "FDA's longstanding policy on compounded drugs is firmly rooted in protecting public health." *Id.* at 45. The Government describes its expansive interpretation of the FDCA's definition of "new drug" to be "[b]ecause of such public health concerns," rather than any congressional implied or expressed intent. Govt. Br. at 4. *See also id.* at 9 (arguing for FDA authority over compounded drugs based on a rationale that they "present concerns about their safety and effectiveness"); *id.* at 10 ("the consequences for the public health can be serious and potentially deadly"); *id.* ("established a policy for addressing the public health issues associated with compounded drugs"). The FDA thereby relies heavily on public policy arguments here.

While the FDA's feigned concern for patients may have superficial appeal, the performance of the FDA proves otherwise. One need look no further than how the FDA has obstructed and impeded the use of lower cost generic drugs in order to realize the medical disaster that would occur if the FDA gained control over compounded drugs. "At a time when the use of low-cost generic drugs is being embraced as one of the few ways to rein in skyrocketing health care costs, the Food and Drug Administration has a backlog of more than 800 applications to bring new generic products to the market -- an all-time high." Marc Kaufman, *Generic Drugs Hit Backlog at FDA: No Plans to Expand Review Capabilities*, Washington Post A01 (Feb. 4, 2006).[1]

This obstruction by the FDA to the sale of generic drugs harms patient care, but obviously helps pharmaceutical companies like the *Amicus* Wyeth, which has intervened here. Suppressing or delaying approval for compounded drugs would help Wyeth enormously by frustrating potential competition for its products. The formula that has worked so well for pharmaceutical companies in keeping generic drugs off the market will be duplicated for compounded drugs, at the expense of patient care. "As a result, experts say,

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[1] http://www.washingtonpost.com/wp-dyn/content/article/2006/02/03/AR2006020302598.html (viewed 6/4/07)

fewer generic drugs will be available to consumers in the years ahead than the industry is ready and able to provide." *Id.*

Does the FDA plan to reduce its delays for approving generic drugs? Not as far as anyone can tell. "The FDA, however, has told Congress that the office that reviews new generics needs no additional money, and the agency has no plans to hire more reviewers." *Id.* Passing laws to speed up this process apparently has no effect. "[B]y statute the agency is obliged to do the job within six months," but "[t]he office took an average of 20.5 months to review each application …." *Id.*

Wyeth and other entrenched pharmaceutical companies obviously do not want more competition from generic drugs, or from compounded drugs. Delays in FDA approval of compounded drugs would help Wyeth and other industrial giants just as they have been helped by the delays in approval of generic drugs. Pharmaceutical giant Wyeth filed an *amicus* brief here to advance its interests, which are not the interests of physicians and the patients they serve.

In 2007, the above backlog has only worsened. The Office of Generic Drugs' "ever-growing backlog of pending applications swelled to 1,172 in fiscal 2006, a 34 percent increase from fiscal 2005. Four months into fiscal 2007, the backlog had grown to 1,293." *FDA Generics Head Says*

Bioequivalence Guides Almost Done, 13 FDA Week No. 10 (Mar. 9, 2007). For the 47 million uninsured patients in America, every day that a generic drug is withheld from the market by the FDA is another day that those patients are deprived of affordable, and even life-saving, medication. The FDA is keeping not just one generic drug from the market, but it is keeping 1,293 from the market, which adversely affects millions of patients on a daily basis.

Given this astounding backlog, a judicial grant to the FDA of authority over compounded drugs would be an unmitigated disaster for physicians and their patients. Classifying compounded drugs as "new drugs" subject to FDA approval would be akin to declaring that patients cannot see their physician until the FDA first inspects the physician's office. The senseless delays and bureaucracy would inflict enormous injury on patient health and safety. Congress declined to give the FDA such sweeping authority over compounding pharmacies for a very good reason: it would be detrimental public policy.

B. Statements by Senators Reinforce that the FDA's Attempt to Expand Its Authority Is Unjustified.

In 1999, two senior members of the United States Senate declared their understanding of the essential role played by compounding 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, has reportedly prepared 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. Whether the FDA is to obtain such power is up to Congress and the President, not for the FDA to decide for itself. 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 usurp the powers of the States, or arrogate power unto itself that has not been granted by Congress.

CONCLUSION

For all the foregoing reasons, the decision below should be affirmed.

Respectfully submitted,

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Dated: June 6, 2007

CERTIFICATE OF SERVICE

I, Andrew L. Schlafly, counsel for *amicus curiae* Association of American Physicians and Surgeons, Inc., hereby certify that two true and complete hard copies, and an electronic copy in Microsoft Word 2002, of the Brief of *amicus curiae* Association of American Physicians and Surgeons, Inc., was served via commercial overnight delivery, on counsel of record as listed below, on this 6th day of June, 2007, to:

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CERTIFICATE OF COMPLIANCE
WITH RULE 32(a) and LOCAL RULE 32.3

1. This brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B) because:

   this brief contains _4,544____ words excluding the parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii).

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3. Undersigned counsel is also providing an electronic version of the brief to the court and opposing counsel.

4. Undersigned counsel understands that a material misrepresentation in completing this certificate, or circumvention of the type-volume limits in Fed.R.App.P. 32(a)(7)(B)(iii), may result in the court's striking the brief and imposing sanctions against the person signing the brief.

Dated: June 6, 2007

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