

**IN THE UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF TEXAS
MIDLAND-ODESSA DIVISION**

MEDICAL CENTER PHARMACY, <i>et al.</i> ,)	
)	
Plaintiffs,)	
)	
v.)	Case No. MO-04-CV-130
)	
JOHN ASHCROFT, <i>et al.</i> ,)	
)	
Defendants.)	

MEMORANDUM OF THE ASSOCIATION OF AMERICAN PHYSICIANS AND SURGEONS, INC., AS *AMICUS CURIAE* IN SUPPORT OF PLAINTIFFS

The *amicus curiae* Association of American Physicians and Surgeons, Inc. (“AAPS”) hereby submits this memorandum in support of Plaintiffs.

I. Interest of *Amicus Curiae* AAPS.

Amicus curiae AAPS is a not-for-profit membership organization founded in 1943. AAPS represents approximately 4,000 physicians nationwide in all practices and specialties, including physicians who make use of compounding pharmacies. AAPS was established to preserve the practice of private medicine and has remained dedicated to the sanctity of the patient-physician relationship, which AAPS believes must be protected from most forms of third-party intervention. AAPS submits this brief to stress the importance of physician discretion to be able to treat the sick in an optimal manner. AAPS views free economic choice by patients, not unwarranted government regulation, as the best means available for improving their medical care.

AAPS is concerned that if compounded drugs are classified as new drugs and regulated by the Food and Drug Administration (“FDA”), then this will inevitably tie the hands of physicians at the expense of quality care for patients. The FDA would ultimately substitute its distorted agenda for treating illnesses for that of the physicians.

AAPS frequently files *amicus curiae* briefs before state and federal courts in defense of the practice of private and ethical medicine. In a case remarkably similar to this one, AAPS succeeded in overturning an FDA rule on the grounds that it exceeded the authority of the FDA, the same issue at bar. *See Ass’n of Am. Physicians & Surgeons, Inc. v. United States Food and Drug Admin.*, 226 F. Supp. 2d 204 (D.D.C. 2002) (hereinafter, *AAPS v. FDA*). In prosecutions, our briefs have helped reverse unjust decisions. *See, e.g., United States v. Dr. Jeffrey Jay Rutgard*, 116 F.3d 1270 (9th Cir. 1997) (overturning an unjust sentence of a physician, as urged by AAPS).

II. Introduction.

Quality medical care requires tailoring treatments, including prescriptions, to individual patient needs. Compounding pharmacies play an essential role in this process, under the direction of physicians. A formula that works well for one patient may do better with adjustments for another. Many patients have medical needs that are not addressed by standard drugs available in the marketplace. Compounding pharmacies fill a gap by enabling physicians to tailor specific drug mixtures for the benefit of certain patients.

It is axiomatic that the FDA should not and cannot replace the role of the physician in deciding optimal medical care for the patients. *See, e.g., Washington Legal Found. v. Henney*, 202 F.3d 331 (D.C. Cir. 2000). “A physician may prescribe a legal drug to serve any purpose

that he or she deems appropriate, regardless of whether the drug has been approved for that use by the FDA.” *Id.* at 333. Conceptually, compounded drugs are analogous to approved drugs prescribed for unapproved uses. Compounded drugs only have ingredients that have been tested for safety and allowed for use by physicians. How physicians then prescribe them is best left to their professional discretion. The FDA lacks authority or justification for attempting to regulate compounding pharmacies.

But as surely as death and taxes advance, the FDA repeatedly seeks power at the expense of physicians and their patients. In *AAPS v. FDA*, *supra*, AAPS successfully obtained an injunction against the FDA from asserting authority to require new drugs for adults to be tested on children, known as the “Pediatric Rule.” The district court enjoined the FDA from enforcing the Pediatric Rule because it lacked statutory authorization:

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.**

226 F. Supp. 2d at 222.

The effect of the disputed FDA oversight of compounding pharmacies would be similar to that of the Pediatric Rule, and the FDA should again fail in its attempt to extend its reach. Physicians are trained and licensed to provide medical care, including prescribing what is best to treat the illnesses of their patients. The FDA lacks this training and licensure. The FDA’s proposed interference with free economic choices will limit the options available to physicians

for treating illness, and should be rejected. Where, as here, Congress has not authorized such regulatory enforcement, it is invalid. “[A]dministrative agencies are vested only with the authority given to them by Congress.” *Gibas v. Saginaw Min. Co.*, 748 F. 2d 1112, 1117 (6th Cir. 1984), *cert. denied*, 471 U.S. 1116 (1985). *See generally INS v. Chadha*, 462 U.S. 919, 954 (1983) (observing that agency action “is always subject to check by the terms of the legislation that authorized it”).

The FDA cannot limit the availability of the most effective pharmaceuticals for the treatment of disease, illness, and other afflictions to AAPS’s physician members unless Congress specifically mandates such interference. It has not. “[A]n administrative agency’s power to promulgate legislative regulations is limited to the authority delegated by Congress.” *Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 208 (1988). Congress has not given the FDA the authority to regulate compounding pharmacies, and it would disrupt the ability of physicians to serve their patients if the FDA were to supplant them. The FDA policies challenged here are not “consistent with the statute under which they are promulgated.” *United States v. Larionoff*, 431 U.S. 864, 873 (1977). “The rulemaking power granted to an administrative agency charged with the administration of a federal statute is not the power to make law. Rather, it is the power to adopt regulations to carry into effect the will of Congress as expressed by the statute.” *Ernst & Ernst v. Hochfelder*, 425 U.S. 185, 213-14 (1976) (citations and internal quotations omitted). This court should enjoin the FDA with respect to asserting regulatory power over compounding pharmacies.

III. Free Enterprise Access to Compounded Drugs Is Essential to Serving Many Patients and Optimizing Their Care.

Ever since Hippocrates, physicians have borne the responsibility and authority for administering the best medical care to the sick. Patients want and need their physicians to have full access to all means available to ameliorate illness. Unlicensed bureaucrats are neither trained nor allowed to substitute their judgment for that of physicians in addressing illness. The “relationship between the physician and his patient ... in many cases is as important to the health of the patient as the medical or surgical treatment administered.” *Owens v. White*, 380 F.2d 310, 315 (9th Cir. 1967) (quotation omitted). Attempts by the FDA to encroach on the ability of physicians to prescribe compounded drugs are as unwise as they are unauthorized.

Just as Congress withholds authority from the FDA to interfere with off-label prescriptions (*i.e.*, unapproved uses of approved drugs), Congress similarly takes a hands-off approach to compounded drugs. “[T]he government agrees with [the physician] that the provisions of the [FDCA] and the regulations of the FDA that are now in force do not prevent him from prescribing for uses not approved by the FDA drugs which have been approved by the FDA for some other purpose.” *United States v. Evers*, 643 F.2d 1043, 1049 (5th Cir. 1981). It is obvious why Congress does not allow agency interference with off-label uses of drugs: physicians are far better situated and more highly trained to decide what is best to treat the illnesses of their patients. No one who is sick wants his physician to have anything less than the maximum options that the free market can provide. Congress sides with patients, and its laws carry this simple message to the FDA: get out of the way.

“Congress did not want to interfere with physicians’ treatment of their patients.” *Chaney v. Heckler*, 718 F.2d 1174, 1180 (D.C. Cir. 1983), *rev’d on other gnds*, 470 U.S. 821 (1985).

That observation applies with particular force here. Patients benefit from compounded drugs because they are effective in treating illnesses. A compounded drug is conceptually identical to using an approved drug for an unapproved application, and Congress does not want agency interference with such innovation. “New uses for drugs are often discovered after FDA approves the package inserts that explain a drug’s approved uses. Congress would have created havoc in the practice of medicine had it required physicians to follow the expensive and time-consuming procedure of obtaining FDA approval before putting drugs to new uses. Thus Congress exempted the practice of medicine from the Act **so as not to limit a physician’s ability to treat his patients.**” 718 F.2d at 1180 (internal quotations omitted, emphasis added).

Congress recognizes that free enterprise is the best mechanism for improving and supplying medical products, including prescription drugs, to physicians for their use in treating illness. Congress has refrained from allowing interference by the FDA in the free and competitive flow of these goods in the market for the benefit of patients. “[W]hen practitioners ‘manufacture, prepare, propagate, compound, or process drugs or devices solely for use in the course of their professional practice,’ they are not subject to the registration requirement that applies to others who engage in such activities.” *United States v. Algon Chemical Inc.*, 879 F.2d 1154, 1160 (3rd Cir. 1989). *See also Cowan v. United States*, 5 F. Supp. 2d 1235, 1240 (1998) (“The *Algon* Court further explains that the limited ‘practice of medicine’ exception is intended to permit doctors who acquire approved and legally available drugs to ‘compound’ those drugs in the course of their practice without first obtaining FDA approval.”).

An expansion in FDA jurisdiction to include compounding pharmacies would have a devastating effect on the ability of physicians to provide the best possible medical care to their patients.

IV. Compounded Drugs are not “New Drugs” to be Regulated by the FDA.

Congress has not considered compounded drugs to be “new drugs” subject to the statutory requirements of the Federal Food, Drug, and Cosmetic Act of 1938 (“FDCA”), as amended, 21 U.S.C.S. § 301 *et seq.* Rather, Congress “exempt[ed] compounded drugs from the FDCA’s ‘new drug’ requirements and other requirements provided the drugs satisfy a number of restrictions.” *Thompson v. Western States Med. Ctr.*, 535 U.S. 357, 364 (2002). This reflects the sensible deference by Congress to practicing physicians and pharmacists, who can react more swiftly to innovation in the market than the bureaucracy can. *See, e.g.*, 21 U.S.C. §§ 360(g)(1) and 374(a)(2)(A) (omitting compounds from the jurisdiction of the FDA).

Pharmacists should be able to compound drugs, already proven to be safe, in ways that the free market of medicine determines are most effective for treating illness. Compounded drugs have none of the safety issues attendant to new drugs, and the FDA should not impede the invisible hand of free enterprise that brings the best and most effective products to market. It is irrational for the FDA to insist on regulating the compounding of drugs already shown to be safe, and free enterprise can yield improvements in compounding more quickly and more effectively than government can.

As a physicians’ organization, AAPS emphasizes how impractical it would be to treat compounded drugs as “new drugs” under 21 U.S.C. §§ 321(p)(1) and (v)(1). The process for obtaining FDA approval for new drugs is so long and expensive that many patients die before they receive much-needed treatment. Americans who are fortunate enough to have the resources necessary to travel abroad to receive treatments, while awaiting FDA approval, must thereby endure needless risk and expense. This makes little sense, and it would be utterly absurd for

compounded drugs that do not even use new ingredients. The prospect of conducting redundant clinical trials for compounded drugs, and incurring unreasonable delays and costs, is unfathomable. Nor would clinical trials be rational: the very purpose of many compounded drugs is to tailor them to individual needs. There is no group that would provide a meaningful sample for testing a compounded drug tailored to one individual.

V. States, Not the Federal Government, Properly Have Jurisdiction over Compounding Pharmacies.

States, not the federal government, regulate pharmacies. *See Thompson v. Western States Med. Ctr.*, 535 U.S. 357, 361 (2002). All states regulate the compounding of drugs. All states have pharmacy boards that enforce pharmacy regulations. Where, as here, Congress has not properly mandated FDA regulation, that power properly remains with the states and the people. Const. Am. X.

There are compelling reasons why legitimate medical care, including the administration of compounded drugs, should remain within the domain of states. “Obviously, direct control of medical practice in the states is beyond the power of the federal government.” *Linder v. United States*, 268 U.S. 5, 18 (1925). Accountability of the regulators is far greater at the state level, where people know each other and legislators are familiar with the communities. Undesired distortions caused by the media are less at the state level. The regulators at the state level are more responsive to the needs of patients and their physicians; state legislators are better able to focus on local problems that may arise. Medical practices and hospitals that rely on the compounding pharmacies are likewise regulated by state authorities, and supervision of compounding pharmacies best resides at the same level. Congress has wisely avoided interfering with the state regulation of pharmacies.

The Supreme Court has repeatedly emphasized the limits on federal overreaching into the state domain. In *United States v. Lopez*, 514 U.S. 549 (1995), the Supreme Court rejected the argument that the federal government could intrude into a traditionally state domain. The Court also refused to allow federal intrusion into other state jurisdictional matters like “family law and direct regulation of education.” *Id.* at 565. The Supreme Court invalidated a federal statute creating a cause of action for domestic violence, rejecting the argument that economic productivity could justify such federal intrusion. See *United States v. Morrison*, 529 U.S. 598, 618 (2000). In *Lopez* and *Morrison*, the Supreme Court prohibited intrusion into the state realms of public health and safety. Where, as here, a federal agency interferes with state jurisdiction *without* statutory authority, there is even greater reason to invalidate the federal action.

VI. Conclusion.

For all the foregoing reasons, *amicus curiae* AAPS respectfully requests that Defendants’ motion to dismiss be denied in its entirety.

Respectfully Submitted,

THE ASSOCIATION OF AMERICAN PHYSICIANS &
SURGEONS, INC.

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CERTIFICATE OF SERVICE

On March 17, 2005, the undersigned attorney certifies that she caused the foregoing to be served by sending it via Federal Express to:

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