IN THE UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

No. 02-10151J

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA,
Plaintiff/Appellant,

v.

RHONDA M. MEDOWS, in her capacity as Secretary of the Agency for Health Care Administration of the State of Florida; and BOB SHARPE, in his capacity as Deputy Secretary of Medicaid, Agency for Health Care Administration of the State of Florida,
Defendants/Appellees.

On Appeal from the Final Judgment of
the United States District Court
for the Northern District of Florida
(Tallahassee Division)
No. 01-00356 CV-4-WS

BRIEF OF WASHINGTON LEGAL FOUNDATION AND ALLIED EDUCATIONAL FOUNDATION AS *AMICI CURIAE* IN SUPPORT OF PLAINTIFFS/APPELLANTS SEEKING REVERSAL

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February 19, 2002

PhRMA v. Medows, et al., Eleventh Circuit Docket No. 02-10151J

CERTIFICATE OF INTERESTED PERSONS AND CORPORATE DISCLOSURE STATEMENT

Counsel for *amici curiae* Washington Legal Foundation, *et al.*, certifies that the following listed persons and entities may have an interest in the outcome of this case:

Allied Educational Foundation (a non-stock, non-profit corporation, proposed *amicus curiae* in support of Appellants)

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Laura Gasho (Appellant's counsel)

Steven A. Grigas (Appellees' counsel)

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PhRMA v. Medows, et al., Eleventh Circuit Docket No. 02-10151J

Pharmaceutical Research and Manufacturers of America (Appellant; a non-profit corporation, organized and existing under the laws of the State of Delaware. PhRMA has no subsidiaries, conglomerates, affiliates, or parent corporations and issues no stock)

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Richard A. Samp (counsel for proposed *amici curiae*)

Bob Sharpe (Appellee; Deputy Secretary of Medicaid, Agency for Health Care Administration for the State of Florida)

Honorable William C. Sherrill, Jr. (U.S. Magistrate Judge, Northern District of Florida (Tallahassee))

Honorable William Stafford (Senior U.S. District Judge, Northern District of Florida (Tallahassee))

Washington Legal Foundation (a non-stock, non-profit corporation, proposed *amicus curiae* in support of Respondents)

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February 19, 2002

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BRIEF OF WASHINGTON LEGAL FOUNDATION AND ALLIED EDUCATIONAL FOUNDATION AS *AMICI CURIAE* IN SUPPORT OF PLAINTIFFS/APPELLANTS SEEKING REVERSAL

INTERESTS OF *AMICI CURIAE*

The interests of *amici curiae* Washington Legal Foundation (WLF) and Allied Educational Foundation (AEF) are set in their attached motion for leave to file *amicus curiae* brief in support of Plaintiffs/Appellants.

STATEMENT OF THE ISSUE

Whether Florida law violates the federal Medicaid statute by creating a state Medicaid drug formulary from which drugs are excluded without the justification that the federal statute requires and for a reason that the federal statute does not allow.

STATEMENT OF THE CASE

In the interests of brevity, *amici curiae* hereby adopt by reference the Introduction and Statement of the Case contained in the brief of Plaintiffs/ Appellants.

In brief, Florida has adopted a law that restricts Medicaid patients' access to prescription drugs. The law is designed as a price-control measure; Florida imposes access restrictions only on those drugs whose manufacturers are unwilling to provide a rebate of at least 25% on the cost of the drugs. The law

has been in effect since July 1, 2001 and apparently is working as planned: sales have dropped sharply for those drugs subject to the access restrictions and have increased significantly for many of the drugs not subject to the restrictions.

It is uncontested that the Florida law imposes access restrictions based solely on sales price. Access restrictions are imposed on *all* products whose manufacturers are unwilling to offer a 25% rebate, without regard to the effectiveness of those drugs and without regard to the availability of other drugs that provide equivalent benefits.

Plaintiff-Appellant Pharmaceutical Research and Manufacturers of America ("PhRMA") has filed suit against the Florida access restriction law, claiming that the restrictions are illegal because they conflict with provisions of the federal Medicaid law. PhRMA contends that the access restrictions adopted by Florida constitute the use of a Medicaid drug "formulary" within the meaning of § 1927(d)(4) of the Social Security Act ("SSA"), 42 U.S.C. § 1396r-8(d)(4), but that Florida has not complied with the prerequisites for the use of such a formulary. Florida responds that its program does not constitute a "formulary" within the meaning of federal law, but rather is a "prior authorization program" permitted under SSA § 1927(d)(5).

PhRMA filed suit against the Florida program on August 7, 2001 in U.S. District Court for the Northern District of Florida, Tallahassee Division, alleging that the Florida program conflicted with SSA § 1927(d)(4) and therefore was invalid under the Supremacy Clause (Article VI, Clause 2) of the Constitution; PhRMA sought an injunction against continuation of the program. On September 20, 2001, the magistrate judge to whom the matter had been referred recommended that PhRMA's motion for a preliminary injunction be denied. Record Excerpts ("RE") 4. The magistrate judge agreed with Florida that its program was a "prior authorization program" permitted under SSA § 1927(d)(5). He found that Florida's program served "the goals of the Medicaid program, to provide drugs to Medicaid beneficiaries at the lowest cost possible." RE4 at 19. He concluded:

> Nor has Plaintiff pointed to any portion of the federal law which forbids a State from seeking additional rebates from drug manufacturers. In the absence of a specific federal statutory provision, a State should be free, as the buyer in the market place, to try to obtain the best price it can.

Id. at 20.

On December 28, 2001, the district court in a brief order adopted the magistrate's report, denied PhRMA's motion for a preliminary injunction and its

cross-motion for summary judgment, and granted defendants' motion to dismiss or, in the alternative, for summary judgment.

SUMMARY OF ARGUMENT

PhRMA's brief spells out in great detail why, under the only logical interpretation of relevant federal statutes, the Florida program must be deemed a "formulary" within the meaning of SSA § 1927(d)(4). *Amici* will not repeat all of those arguments here, but rather will emphasize only a few of the critical determinants.

First, Congress quite clearly intended in 1990 to prohibit a type of State program that it referred to as a "formulary." It changed the law in 1993, to permit "formularies" under very limited circumstances. *See* SSA § 1927(d)(4). PhRMA has demonstrated that the Florida program has all the features of the "formularies" that Congress intended to restrict. Florida's principal defense is that it no longer calls its program a "formulary" (although that was the name repeatedly applied to it by the Florida legislature and the name Florida administrators used prior to the filing of this lawsuit). But it cannot be the case that a State may evade § 1927(d)(4)'s restrictions by applying a new name to its program, if the program serves the precise function of the "formularies" that

Congress severely restricted. Unless Florida can explain to the Court just what types of programs were intended to be barred by § 1927(d)(4) and why such programs are materially different from the Florida program challenged in this case, the Florida program must be deemed impermissible.

Second, *amici* respectfully suggest that the Court focus on § 1927(d)(4)(D). Under that provision, a State that excludes a drug from its "formulary" – based on, for example, a finding that "the excluded drug does not have a significant, clinically meaningful therapeutic advantage in terms of safety, effectiveness, or clinical outcome . . . over other drugs included in the formulary" (*see* § 1927(d)(4)(C)) -- is required to create a "prior authorization program" under § 1927(d)(5) and to permit the excluded drug to be covered pursuant to the terms of that prior authorization program. Section 1927(d)(4)(D) makes absolutely no sense under Florida's interpretation of the statute. A State wishing to set up a "formulary" under § 1927(d)(4) is required to meet numerous procedural requirements and to make numerous clinical findings before it is allowed to exclude a drug from its formulary -- and even then, as § 1927(d)(4)(D) makes clear, the State can impose no greater access restrictions on the excluded drugs than Florida has imposed under its alleged "prior authorization program." Why

would a State ever jump through all those hoops if it could accomplish the same ends by simply renaming its "formulary" a "prior authorization program?" The answer, of course, is that it would never do so, with the result that the restrictions that Congress intended to impose on State programs would come to nothing.

An examination of the purposes underlying the congressional restrictions on formularies helps to illustrate why the Florida program runs afoul of federal law. The federal government (which provides more than one-half of the costs of Medicaid in Florida) has no more desire than Florida to pay any more than necessary to purchase prescription drugs for Medicaid recipients. Formularies can be an effective tool in holding down costs while at the same time ensuring that patients are receiving the most cost-effective medications. But Congress became concerned that state formularies operated before 1990 were being used as cost-cutting tools without regard to their effect on patient care, and drugs for which there was no adequate substitute were being excluded because States did not want to pay for them. That is why Congress prohibited state Medicaid formularies altogether between 1990 and 1993 and allowed their reintroduction in 1993 on an extremely restricted basis. Whatever one wants to call the Florida

program at issue in this case, it is undisputed that it suffers from the very same deficiency that characterized state formularies prior to 1990: it restricts patient access to certain drugs without regard to whether an equally effective alternative drug is available without restrictions. Regardless whether the program ultimately produces cost savings, it is poor health care policy.

One other salient feature of Congress's 1990 policy initiative was its implementation of a rebate program on a nationwide basis. The result is that all states share equally in the cost savings. The Florida program upsets that balance; it attempts to reduce Medicaid prescription drug costs to a level below those in other States. *Amici* are opposed to any artificial price-control schemes of the type being attempted in Florida; *amici* believe that such schemes undermine health care in this country in the long-term by reducing incentives for the development of new life-saving products. But more importantly for purposes of this case, Florida's price-control scheme undermines the national pricing uniformity that Congress intended in 1990 when it prohibited state Medicaid formularies and replaced them with a nationwide rebate program which guaranteed participating manufacturers equal access to Medicaid recipients in all 50 States.

ARGUMENT

I. THE FLORIDA PROGRAM MUST BE DEEMED A "FORMULARY" WITHIN THE MEANING OF § (d)(5)

In mandating its new access-restriction law, the Florida legislature had no doubt that it was creating a "formulary"; indeed, its stated purpose was to authorize the Agency for Health Care Administration ("AHCA") to "establish a preferred drug formulary in accordance with 42 U.S.C. s. 1396r-8 [SSA § 1927]." The law repeatedly makes reference to a "formulary," as did AHCA before this lawsuit was filed. Those references stopped only after AHCA realized how inconvenient they were for its position in this lawsuit -- because it is uncontested that the Florida access restriction program does not comply with the restrictions imposed on "formularies" by SSA § 1927(d)(4).

Despite the change in nomenclature, the Florida access restriction program meets all of the statutory criteria for a "formulary" and thus should be deemed, in fact, to be a "formulary" within the meaning of SSA § 1927(d)(4). Rather than repeating the complete and persuasive statutory analysis contained in PhRMA's brief, *amici* will emphasize only a few of the critical points.

First, there is little merit to Florida's position that a program ceases to be a "formulary" once a State no longer calls it by that name. When Congress acted

to prohibit State Medicaid "formularies" in 1990, it had a very specific type of program in mind. Numerous states had adopted programs referred to as State Medicaid "formularies"; in general, these programs were designed to control costs by requiring prior authorization for drugs that the States deemed too expensive. *Hearing on S. 2605 and S. 3029 before the Subcomm. on Health for Families and the Uninsured of the Senate Comm. on Finance*, 101st Cong., 2d Sess. 26 (1990) ["1990 SENATE HEARING"]. Congress became concerned that such programs were unduly interfering with patient access to prescription drugs. *Id.* It was those concerns that led Congress, as part of the Omnibus Budget Reconciliation Act of 1990, to prohibit State Medicaid "formularies." *See* Pub. L. No. 101-508, § 4401(a)(2)(C), 104 Stat. 1388-143 (1990). While the law was amended in 1993 to add SSA § 1927(d)(4) and thereby permit States once again to operate Medicaid "formularies," the law includes numerous restrictions on the make-up and activities of such formularies. It is uncontested that the Florida access restriction program does not comply with the § 1927(d)(4) restrictions.

By all accounts, the Florida access restriction program operates in precisely the same manner as the State Medicaid "formularies" to which Congress called a halt in 1990. Florida nonetheless insists that its program

should not be deemed a "formulary" within the meaning of § 1927(d)(4). That position is not credible, given Florida's inability to articulate a meaningful difference between its program and the formularies disapproved by Congress in 1990 (virtually all of which included a prior-authorization feature similar to Florida's). Unless Florida can explain to the Court just what types of programs were intended to be barred by § 1927(d)(4) and why such programs are materially different from the Florida program challenged in this case, the Florida program must be deemed impermissible.

Second, *amici* respectfully suggest that the Court focus its analysis on SSA § 1927(d)(4)(D). Under that provision, a State that excludes a drug from its "formulary" is *required* to create a "prior authorization program" under § 1927(d)(5) and to permit the excluded drug to be covered pursuant to the terms of that prior authorization program.[1] If Florida's interpretation of SSA § 1927 is

[1] The principal purpose of a well-run formulary is to permit a payor to discourage use of drugs that do not provide any unique advantages to patients and may be more expensive, or at least less cost-effective, than other drugs whose use is encouraged. Thus, SSA § 1927(d)(4)(C) authorizes duly constituted formulary committees, after careful review, to determine that a specific drug "does not have a significant, clinically meaningful therapeutic advantage in terms of safety, effectiveness, or clinical outcome . . . over other drugs included in the formulary" with respect to "the treatment of a specific disease or condition for an identified population." If such a determination is made, then the drug may be excluded from a State Medicaid formulary.

accepted, then § 1927(d)(4)(D) makes absolutely no sense. A State wishing to set up a "formulary" under § 1927(d)(4) is required to meet numerous procedural requirements and to make numerous clinical findings before it is allowed to exclude a drug from its formulary -- and even then, as § 1927(d)(4)(D) makes clear, the State can impose no greater access restrictions on the excluded drugs than Florida has imposed under its alleged "prior authorization program." Why would a State ever jump through all those hoops if it could accomplish the same ends by simply renaming its "formulary" a "prior authorization program?" The answer, of course, is that it would never do so, with the result that the restrictions that Congress intended to impose on State programs would come to nothing.

The magistrate judge's effort to give meaning to § 1927(d)(4)(D), while still accepting Florida's interpretation of the statute, was unavailing. The magistrate judge stated:

> Plaintiff argues that the federal statute provides that if a State *excludes* a drug for lack of significant therapeutic value, it must still make the drug available pursuant to the prior authorization program. Plaintiff argues from this that a prior authorization program is permitted for only this purpose, and not for the purpose adopted by Florida. But Plaintiff has pointed to nothing in the federal law which prohibits Florida from creating a prior authorization program for another purpose.

RE4 at 20.

That argument misapprehends the import of § 1927(d)(4)(D). That section demonstrates that a "prior authorization program" under § (d)(5) is a key component of any valid State Medicaid formulary established under § (d)(4). Accordingly, the mere fact that Florida permits coverage under a "prior authorization program" of drugs excluded from its list of preferred drugs is no evidence whatsoever that the Florida program does not constitute a § (d)(4) "formulary." In the absence of any other evidence from Florida that its program is in any way distinguishable from the "formularies" that Congress intended to restrict, the Florida program must be deemed to conflict with federal law.

II. OPERATION OF A FORMULARY BASED SOLELY ON COST CONSIDERATIONS IS POOR HEALTH CARE POLICY, AND THAT IS WHY CONGRESS ACTED TO RESTRICT THEIR USE BY THE STATES

In reining in State formularies in 1990 and 1993, Congress was quite properly concerned that patient health care suffers when formularies are operated solely on the basis of cost concerns.

Numerous studies demonstrate that basing prescription drug coverage on cost considerations -- as Florida undeniably is doing here -- can lead to serious health concerns and does not necessarily even save money in the long run.

Patients who are denied (for cost reasons) the most effective prescription drugs often end up with otherwise-avoidable hospital stays. For example, a recent study in the New England Journal of Medicine described the negative impacts of a New Hampshire Medicaid provision that limited some program participants to three prescriptions per month. Although the policy reduced drug costs by 35%, nursing home admissions rose by 60%, and system-wide medical costs rose as well. The experience with program participants suffering from schizophrenia was particularly revealing. Caps on newer drugs saved $57 per patient annually but led to $1,530 in additional per-patient costs for visits to clinics and emergency rooms. S. Souneri, *et al.,* "Effects of Medicaid Drug Limits on Admissions to Hospitals," *New England Journal of Medicine,* 325 (1991) at 1072-77.

Canada imposes strict limits on government-funded access to prescription drugs. A recent survey of British Columbia doctors found that 27% of them had been forced to admit patients to hospitals as a result of government-mandated substitutions of prescription drugs. William McArthur, "Canadian Medicine Isn't Cheap or Effective," *The Wall Street Journal*, Jan. 21, 2000, at A19.

Accordingly, the magistrate judge was not accurately characterizing federal

Medicaid law when he asserted, "In the absence of a specific federal statutory provision, a State should be free, as any buyer in the marketplace, to try to obtain the best price it can." RE4 at 20. That assertion turns a blind eye to Congress's well-founded concern that dispensing prescription drugs based solely on cost consideration can have very negative health effects. A State is not free to make an end-run around those concerns by removing the word "formulary" from its program and then insisting that there is no "specific federal statutory provision" that bars what the State is doing.

Amici also respectfully suggest that the price-control scheme adopted by Florida is bad long-term public policy because it will stifle pharmaceutical research, with the inevitable result that fewer life-saving drugs will be developed. Any claims, such as those asserted by Florida, that drug costs are too high must take into account the tremendous cost of new product development. On average, it costs anywhere from $500 million to $1 billion in research and development (R&D) costs to get a drug approved for use in the United States. "Drug Price Controls: A `Cure' Worse Than the Disease," The Independent Institute (2000). Once the drug is approved, the costs of manufacturing and distributing the drug are relatively low. However, basic economics dictate that pharmaceutical

companies must recover all their costs, plus a reasonable profit, in order to spur them to continue to develop new medicines. As one expert has noted:

> Any attempt to regulate pharmaceutical prices on the basis of cost. . . will be imprecise and arbitrary. Regulators are tempted to set prices to cover only those costs that are clearly attributable to the delivery of particular drugs to particular market segments. That narrow focus tends to result in prices that are too low to cover R&D, therefore stifling innovation and competition.

Patricia M. Danzon, "Making Sense of Drug Prices," 23 REGULATION at 62-63 (2000).

Congress has attempted to balance the need to control prescription drug costs with its desire to maintain incentives for further research. When Congress prohibited State Medicaid formularies in 1990, it simultaneous adopted a rebate program on a nationwide basis. The result is a pricing structure that has not stifled R&D and a system under which all States share equally in the cost savings. The Florida program upsets that balance; it attempts to reduce Medicaid prescription drug costs to a level below those in other States. By mandating equal access to Medicaid recipients nationwide for the drugs of all manufactures that agreed to pay the nationwide rebate of 15.1%, Congress indicated its disapproval of State efforts to impose further price controls and to seek to, in effect, foist their prescription drug costs onto other States.

CONCLUSION

Amicus curiae respectfully request that the judgment of the district court be reversed.

Respectfully submitted,

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Dated: February 19, 2002

CERTIFICATE OF COMPLIANCE

I am an attorney for *amici curiae* Washington Legal Foundation (WLF), *et al*. Pursuant to Fed.R.App.P. 32(a)(7)(C), I hereby certify that the foregoing brief is in 14-point, proportionately spaced CG Times type. According to the word processing system used to prepare this brief (WordPerfect 6.0), the word count of the brief is 3,567, not including the corporate disclosure statement, table of contents, table of authorities, certificate of service, and this certificate of compliance.

_____
Richard A. Samp

CERTIFICATE OF SERVICE

I hereby certify that on this 19th day of February, 2002, two copies of the brief of *amici curiae* WLF, *et al.,* in support of Plaintiff-Appellee were deposited in the U.S. Mail, with first-class postage affixed, addressed as follows:

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