ORAL ARGUMENT SCHEDULED FOR DECEMBER 12, 2003

No. 03-5117

IN THE UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

PHARMACEUTICAL RESEARCH AND
MANUFACTURERS OF AMERICA,
Plaintiff-Appellant,
and

NATIONAL URBAN INDIAN COALITION and
NATIONAL ALLIANCE FOR THE MENTALLY ILL OF MICHIGAN,
Intervenor Plaintiffs-Appellants,
v.

TOMMY G. THOMPSON, *et. al.,*
Defendants-Appellees,

On Appeal from the United States District Court
for the District of Columbia

BRIEF OF WASHINGTON LEGAL FOUNDATION, THE KIDNEY CANCER ASSOCIATION, THE 60 PLUS ASSOCIATION, and THE ALLIED EDUCATIONAL FOUNDATION, AS *AMICI CURIAE* IN SUPPORT OF APPELLANT AND INTERVENOR-APPELLANTS, URGING REVERSAL

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September 15, 2003

CERTIFICATE AS TO PARTES, RULINGS, AND RELATED CASES

Pursuant to Circuit Rule 28(a)(1), the undersigned counsel of record certifies as follows:

A. PARTIES AND *AMICI*

All parties, intervenors, and *amici* appearing before the district court and in this Court are listed in the Brief for Appellant, except for the Washington Legal Foundation (WLF), the Kidney Cancer Association (KCA), the 60 Plus Association (60 Plus), and the Allied Educational Foundation (AEF).

WLF, KCA, 60 Plus, and AEF are non-profit, non-stock corporations organized under § 501(c) of the Internal Revenue Code. They have no parent companies, and no publicly held company has any ownership interest in them. WLF is a public-interest law and policy center that regularly litigates in the courts in support of free-enterprise principles. KCA is a research, education, and advocacy group that pursues the goal of a world without kidney cancer. 60 Plus is advocacy group that seeks to promote the interests of elderly Americans. AEF is a charitable and educational group that promotes sound public policymaking.

B. RULINGS UNDER REVIEW

References to the rulings at issue appear in the Brief for Appellant.

C. RELATED CASES

Amici curiae state that they are aware of no related cases pending in this Court or any other court of appeals involving substantially the same parties and the same or similar issues.

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GLOSSARY

DCH	Michigan Department of Community Health
HHS	U.S. Department of Health and Human Services
NAMI	National Alliance of the Mentally Ill of Michigan
NUIC	National Urban Indian Coalition
PhRMA	Pharmaceutical Research and Manufacturers of America
Secretary	Tommy G. Thompson, in his official capacity, Secretary of the U.S. Department of Health and Human Services
SSA	Social Security Act

INTERESTS OF *AMICI CURIAE*

The Washington Legal Foundation (WLF) is a public-interest law and policy center with supporters in all 50 states, including many in the State of Michigan. WLF devotes a significant portion of its resources to defending and promoting free enterprise, individual rights, and a limited and accountable government. In particular, WLF has appeared in numerous court proceedings in opposition to government efforts to restrict prescription drug sales. *See, e.g., Pharmaceutical Research & Manufacturers of America v. Walsh*, 123 S. Ct. 1855 (2003); *Pharmaceutical Research & Manufacturers of America v. Medows*, 304 F.3d 1197 (11th Cir. 2002), *cert. denied,* 123 S. Ct. 2213 (2003). WLF also filed briefs in the Michigan courts in a state-law challenge to the Michigan program at issue in this case. *Pharmaceutical Research & Manufacturers of America v. Dep't of Community Health*, 254 Mich. App. 397 (2002), *leave to appeal denied,* 663 N.W.2d 475 (Mich. 2003).

The Kidney Cancer Association is a patient and survivor-led voluntary health agency pursuing the goal of a world without kidney cancer through research, education, and advocacy.

The 60 Plus Association is a Virginia-based seniors' advocacy group devoted to the free market, free enterprise system. 60 Plus is opposed to price controls on prescription drugs because: (1) they stifle pharmaceutical research

leading to the medical miracles enabling seniors to live longer and better and stay out of hospitals; and (2) they result in shortages, as evidenced by the shortcomings of the Canadian health care system.

The Allied Educational Foundation (AEF) is a non-profit charitable and educational foundation based on Englewood, New Jersey. Founded in 1964, AEF is dedicated to promoting education in diverse areas of study, such as law and public policy, and has appeared as *amicus curiae* in this Court on a number of occasions.

Amici curiae are extremely interested in optimal health-care delivery in this country. Prescription drugs play an increasingly important role in our nation's health care system. Although drug spending represents only a small share of national health-care spending -- 9 cents out of every health-care dollar -- increased spending on prescription drugs is a very positive health-care trend. Studies have shown that increased drug spending not only improves overall public health but also results in *decreased* overall costs.

Amici are concerned that the Michigan program will have long-term adverse effects on health care in this country. The program threatens to interfere with Medicaid recipients' access to the best-available pharmaceuticals. The result will be reduced levels of public health and, in the long run, increased health-care costs.

Moreover, by interfering with the free market in pharmaceutical sales, the program threatens to discourage research and development of new, life-saving drugs and to Balkanize what is now an efficient and uniform Medicaid rebate program.

Amici are also concerned that Michigan's program to reduce prescription drug spending will end up denying Medicaid patients access to much-needed medication. The result will be reduced levels of public health and, in the long run, increased health-care costs. *Amici* do not believe that Congress intended to permit such a program.

The Court issued an order on September 9, 2003, granting *amici*'s motion for leave to file this brief.

ISSUES PRESENTED FOR REVIEW

Amici address the following issue only:

Whether the Secretary exceeded his statutory authority or acted arbitrarily or capriciously in approving a Medicaid prescription drug program that creates a prescription drug formulary but does not comply with the express limitations on excluding drugs from such formularies set forth in 42 U.S.C. § 1396r-8(d)(4).

STATUTORY PROVISIONS INVOLVED

Pertinent statutory provisions are reprinted in the Addendum to the Brief for Appellant.

STATEMENT OF THE CASE

Amici hereby adopt by reference the Statement of the Case and Statement of Facts set forth in the Brief for Appellant.

In brief, Michigan has adopted a program (the "Michigan Initiative") that restricts Medicaid patients' access to prescription drugs. The program is designed as a price-control measure; Michigan imposes access restrictions on certain drugs whose manufacturers are unwilling to pay supplemental rebates that reduce the effective prices of those drugs, and no access restrictions are imposed on manufacturers who pay supplemental rebates. The U.S. Department of Health and Human Services (HHS) approved the Michigan Initiative on January 24, 2002. The Michigan Initiative has been in effect since February 25, 2002 and apparently is working as planned: sales have dropped sharply for those drugs subject to the access restrictions.

Plaintiff-Appellant Pharmaceutical Research and Manufacturers of America ("PhRMA") filed suit against the HHS Secretary in June 2002, claiming that HHS's approval of the program violated the Administrative Procedure Act (APA) because the program conflicted with the U.S. Constitution's Commerce Clause and various provisions of the federal Medicaid law. PhRMA contended, *inter alia,* that the access restrictions adopted by Michigan 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 Michigan has not complied (and has indicated that it will not comply) with the prerequisites for the use of such a formulary. HHS and Michigan responded that the Michigan Initiative does not contemplate use of a "formulary" within the meaning of federal law, but rather is a "prior authorization program" permitted under SSA § 1927(d)(5), 42 U.S.C. § 1396r-8(d)(5).

PhRMA filed suit against the Secretary (as well as the Administrator of the Centers for Medicare and Medicaid Services (CMS)) in U.S. District Court for the District of Columbia.[1] On July 29, 2002, the district court granted a motion to intervene as a defendant filed by the Michigan Department of Community Health (DCH). In August 2002, the court granted motions to intervene as plaintiffs filed by the National Alliance for the Mentally Ill of Michigan (NAMI, an organization that represents the interests of the mentally ill in Michigan and their families) and the National Urban Indian Coalition (NUIC, an organization that represents the interests of American Indians living in urban areas, many of whom are Medicaid recipients).

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[1] The Secretary and the Administrator are hereinafter referred to jointly as the "Secretary" or the "federal defendants."

On March 28, 2003, the district court issued a Memorandum Opinion and Order, denying motions for summary judgment filed by PhRMA, NAMI, and NUIC; granting cross-motions for summary judgment filed by the Secretary and the Michigan DCH; and entering judgment in favor of defendants on all claims. *Pharmaceutical Research and Manufacturers of America v. Thompson,* 259 F. Supp. 2d 39 (D.D.C. 2003). In particular, the district court rejected PhRMA's claim that Michigan had established a "illegal formulary" in violation of SSA § 1927(d)(4). Slip Op. 32-42.

The district court stated that the interpretation of SSA § 1927 espoused by the Secretary and DCH "leaves something to be desired." *Id.* 35. The court said that the Secretary's interpretation "fails to imbue the term 'formulary' with any definite content" and "fail[s] to explain what a formulary actually is under their construct and thus when the requirements of § 1396r-8(d)(4) would apply." *Id.* 36. The court nonetheless upheld the Secretary's decision on the ground that the statute "could not be clearer in specifying that states need not follow the procedures for excluding drugs from formularies in order to subject drugs to prior authorization." *Id.* 39. Although apparently troubled that its reading of the Medicaid statute robbed SSA § 1927(d)(4) of significance, the court said that "it was bound to follow Congress's intent, and the intent here is clearly inconsistent

with PhRMA's and NUIC's narrow understanding of the states' prior authorization powers." *Id.* 42. The court suggested that there might be some minor significance to a state's decision to invoke § 1927(d)(4) to exclude a drug from its formulary: although excluded drugs are still eligible for Medicaid reimbursement pursuant to the § 1927(d)(5) prior authorization procedures, such an exclusion might make it more difficult for a manufacturer to market the drugs to non-Medicaid providers (in comparison to drugs subjected to prior authorization but not excluded from a State's formulary). *Id.*

SUMMARY OF ARGUMENT

The briefs of PhRMA and NUIC/NAMI spell out in great detail why, under the only logical interpretation of relevant statutes, the Michigan initiative 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 points.

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 Michigan Initiative has all the features of the "formularies" that Congress intended to restrict. The Secretary's principal defense

of his decision to approve the program is that Michigan does not call its program a "formulary" (although that name was 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 the Secretary 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 Michigan Initiative challenged in this case, his approval of the Michigan program must be deemed an abuse of discretion.

Second, the district court's reliance on SSA §§ 1927(d)(1)(A) and (d)(5) was misplaced. Far from providing States with virtually unlimited authority to impose prior authorization requirements, those provisions are more plausibly interpreted in a far narrower fashion that does not have the effect of writing § 1927(d)(4) out of the Medicaid statute.

An examination of the purposes underlying the congressional restrictions on formularies helps to illustrate why the Michigan program runs afoul of federal law. The federal government (which provides more than one-half of the costs of Medicaid in Michigan) has no more desire than Michigan 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 Michigan Initiative, 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 solely as a cost saving measure -- such access is restricted only if the price is too high from the State's perspective. Regardless whether the program ultimately produces cost savings, it is poor health care policy.

ARGUMENT

I. THE MICHIGAN INITIATIVE MUST BE DEEMED TO CREATE A "FORMULARY" WITHIN THE MEANING OF § (d)(4)

When, as part of its new program, Michigan mandated creation of a list of "preferred" drugs that would be available under Medicaid without prior approval and without manufacturer payment of supplemental rebates, there can be little

doubt that Michigan thought it was creating a "formulary" within the meaning of SSA §1927(d)(4). Indeed, the State established its Michigan Pharmacy and Therapeutics Committee (the "Michigan Committee," the committee charged with creating a list of "preferred" drugs) in the precise manner specified by SSA § 1927(d)(4)(A) for committees charged with establishing "formularies."

After this lawsuit was filed, it became inconvenient for Michigan to refer to the "preferred" drug list created by the Michigan Committee as a "formulary," and it has refrained from doing so. Nonetheless, the Michigan access restriction program meets all the statutory criteria for a "formulary" and thus should be deemed to be a "formulary" within the meaning of SSA § 1927(d)(4). Rather than repeating the complete and persuasive statutory analyses contained in the briefs of PhRMA and NUIC/NAMI, *amici* will emphasize only a few of the critical points.

A. The District Court Erred in Reading into the SSA Broad-Ranging Authority for the Secretary and States to Impose Prior Authorization Requirements on HHS-Approved Drugs

The district court was clearly troubled by the Secretary's reading of the SSA. The court recognized that if (as urged by the Secretary) it interpreted the SSA as granting States virtually unfettered authority to impose "prior authorization" requirements on drugs administered under the Medicaid program, SSA § 1927(d)(4)'s strict limitation on State's creation of drug formularies would be

rendered a dead letter. Slip Op. 35-36. The court nonetheless upheld the Secretary's approval of the Michigan Initiative (despite Michigan's noncompliance with the requirements for formularies imposed by § 1927(d)(4)) because it interpreted the language of the SSA as granting extremely broad "prior authorization powers" to the States. Slip Op. 41.

The district court's conclusion was based on a mistaken premise: the SSA does not, in fact, grant States the extremely broad prior authorization powers that the court read into the statute. First, the court's reliance on SSA § 1927(d)(1)(A), 42 U.S.C. § 1396r-8(d)(1)(A), is misplaced. Section 1927(d)(1)(A) provides:

> (1) Permissible restrictions
>
> > (A) A State may subject to prior authorization any covered outpatient drug. Any such prior authorization program shall comply with the requirements of paragraph (5).

The district court interpreted this language to mean that States are authorized to impose "prior authorization" requirements on *any* drug under *any* circumstances, provided only that the State comply with the minimal restrictions imposed by § 1927(d)(5). Slip Op. 39. But that is not the only permissible interpretation of § 1927(d)(1)(A), and that statutory provision is certainly not the "unequivocal" grant of broad "prior authorization" authority that the district court viewed it to be. *Id.* Even viewing § 1927(d)(1)(A) in isolation, an equally

plausible interpretation is that Congress was making clear that no drug should be categorically exempted from States' "prior authorization" authority but that it was not thereby attempting to set out the precise circumstances under which that authority could be exercised. Indeed, as discussed more fully below, when § 1927(d)(1)(A) is read in conjunction with other provisions of the SSA -- particularly SSA §§ 1927(d)(1)(B) and 1927(d)(4) -- the only plausible interpretation of § 1927(d)(1)(A) is the latter (and narrower) interpretation set out above.

Second, the district court relied on the language of SSA § 1927(d)(5), 42 U.S.C. § 1396r-8(d)(5), which provides:

> Requirements for prior authorization program
>
> A State plan under this subchapter may require, as a condition of coverage or payment for a covered outpatient drug for which Federal financial participation is available in accordance with this section, with respect to drugs dispensed on or after July 1, 1991, the approval of the drug before its dispensing for any medically accepted indication (as defined in subsection (k)(6) of this section [42 U.S.C. § 1396r-8(k)(6)]) *only if* the system providing for such approval--
>
> > (A) provides response by telephone or other telecommunication device within 24 hours of a request for prior authorization; and
> >
> > (B) except with respect to drugs on the list referred to in paragraph (2) [42 U.S.C. § 1396r-8(d)(2)], provides for the dispensing of at least 72-hour supply of a covered outpatient prescription drug in an emergency situation (as defined by the Secretary).

42 U.S.C. § 1396r-8(d)(5) (emphasis added).

The district court interpreted § (d)(5) as though it authorized State prior authorization programs "if, and only if" a State plan met the two prerequisites set forth therein. But of course, the statute does not contain such "if, but only if" language; rather, it provides that States may require prior authorization "only if" the two prerequisites are met. By far the most plausible interpretation of that language is that Congress intended that States must, at a minimum, comply with the two prerequisites set forth in § (d)(5) before imposing a prior authorization requirement, but that Congress was not ruling out the possibility that other provisions of the SSA imposed other limitations on prior authorization requirements. As discussed below, SSA § 1927(d)(4) imposes just such additional limitations.

The district court ruled several months before the Supreme Court issued its decision in *Pharmaceutical Research and Manufacturers of America v. Walsh,* 123 S. Ct. 1855 (2003), and thus did not have the benefit of the Supreme Court's most recent analysis of the Medicaid laws. But nothing in the various *Walsh* opinions supports the district's interpretation of SSA § 1927(d).

Walsh involved an ongoing challenge to a program adopted by the State of Maine (the "Maine Rx Program") that provides retail drug discounts to Maine

residents who lack private health insurance and are not enrolled in Medicaid. The Maine Rx Program requires drug manufacturers to subsidize those discounts.[2] Maine threatens to impose, in connection with its operation of the State's Medicaid program, a "prior authorization" requirement on the drugs of any manufacturer that refuses to provide subsidies to the State. PhRMA argues, *inter alia*, that the threat to impose a "prior authorization" under those circumstances violates the Medicaid laws because it is inconsistent with the statutory mandate that care and services be provided "in a manner consistent with . . . the best interests of the recipients." 42 U.S.C. § 1396a(a)(19).

The Supreme Court issued a judgment affirming the appeals court's decision reversing the district court's preliminary injunction against the Maine Rx Program; it remanded the case to the district court for trial. However, the Court was badly splintered; it issued five separate opinions, with no single opinion garnering majority support. The plurality opinion stated that the Maine RX Program would be inconsistent with 42 U.S.C. § 1396a(a)(19) if, at trial, PhRMA could

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[2] Maine acted to ease financial burdens faced by uninsured lower- and middle-income residents whose income exceeded Medicaid limits but who nonetheless had difficulty affording prescription drugs. In this case, Michigan has decidedly less altruistic motives for seeking to impose prior authorization requirements: it is seeking to lower its own costs. Michigan has never indicated that it will use cost reductions generated by the Michigan Initiative to fund other medical services for Medicaid-eligible individuals.

demonstrate that a "significant number" of Medicaid patients' medical needs are "adversely affected" by the program. *Walsh,* 123 S. Ct. at 1870 (three-judge plurality). More importantly for purposes of this case, the distinction between a "formulary" and a "prior authorization" program was not at issue in *Walsh*, and none of the Court's five opinions so much as cited SSA § 1927(d)(4). Accordingly, *Walsh* has absolutely no bearing on PhRMA's contention that HHS erred in approving the Michigan Initiative because it is inconsistent with § 1927(d)(4)'s restrictions on the use of formularies.

In the introductory portion of his opinion, Justice Stevens includes some general language regarding prior authorization requirements and mentions § 1927(d)(5). But this discussion of § 1927(d)(5) is clearly *dicta*, given that it is included in Part I of the opinion (the introduction) and that the meaning of § 1927(d)(5) was not at issue in *Walsh*. *Walsh,* 123 S. Ct. at 1862.[3]

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[3] Part I of Justice Stevens's opinion was joined by seven justices: Justices Stevens, Souter, and Ginsburg (who joined the entire opinion); Justice Breyer (who joined the opinion in part); and Chief Justice Rehnquist and Justices O'Connor and Kennedy (who dissented from Justice Stevens's conclusion that PhRMA was unlikely to prevail on its statutory claims). Thus, although Part I's introductory material technically constitutes the opinion of the Court, even if it were not merely *dicta* it could not plausibly be deemed to provide a binding interpretation of § 1927(d)(5). Three of the seven justices who joined Part I made clear that they fundamentally disagreed with Justice Stevens's understanding of the permissible purposes of prior authorization programs. *Walsh,* 123 S. Ct. at 1879-80 (O'Connor, J., concurring in part and dissenting in part).

B. Unless the Michigan Initiative Is Deemed a "Formulary" Within the Meaning of § (d)(4), that Provision Is Deprived of All Meaning

In order to determine whether Congress intended to authorize State plans such as Michigan, the Court needs to look at the Medicaid statute as a whole. A federal statute must be interpreted "as a symmetrical and coherent regulatory scheme"; courts must make every effort to "fit, if possible, all parts [of the scheme] into a harmonious whole." *FDA v. Brown & Williamson Tobacco Corp.,* 529 U.S. 120, 133 (2000) (citations omitted). *Amici* respectfully submit that it is PhRMA's interpretation of SSA § 1927(d)(4) that best harmonizes the various provisions of the Medicaid statute.

The briefs of PhRMA, NUIC, and NAMI have explained cogently why the district court's interpretation of the Medicaid statute essentially writes § 1927(d)(4) out of the law, in violation of the standard rules of statutory construction set forth in *Brown & Williamson* and elsewhere.[4] *Amici* seek only to highlight of few of the points made in those briefs.

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

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[4] Indeed, the district court essentially conceded that § 1927(d)(4) has little meaning under its interpretation of the Medicaid statute. Slip Op. 41-42.

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 Michigan Initiative does not comply with the § 1927(d)(4) restrictions.[5]

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[5] For example, SSA § 1927(d)(4)(C) requires that if a State wishes to exclude a drug from a formulary, it must provide "a written explanation (available to the public) of the basis for the exclusion," and any such exclusion must be based on the criteria set out therein. Michigan has not provided a "written explanation" of the bases for a determination that certain drugs -- made by companies that have refused to pay supplemental rebates -- meet the criteria for exclusion under § 1927(d)(4)(C).

By all accounts, the Michigan Initiative operates in the same manner as the State Medicaid "formularies" to which Congress called a halt in 1990. The Secretary nonetheless insists that the Michigan program should not be deemed a "formulary" within the meaning of § 1927(d)(4). That position is not credible, given the Secretary's inability to articulate a meaningful difference between Michigan's program and the formularies disapproved by Congress in 1990 (virtually all of which included a prior-authorization feature similar to Michigan's). Unless the Secretary 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 Michigan program challenged in this case, the Secretary's approval of the Michigan Initiative 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.[6] If the Secretary's interpretation of SSA

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[6] 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 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

§ 1927 is 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 Michigan 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.

In *Pharmaceutical Research and Manufacturers of America v. Medows,* 304 F.3d 1197 (11th Cir. 2002), *cert. denied,* 123 S. Ct. 2213 (2003), the U.S. Court of Appeals for the Eleventh Circuit was faced with a challenge to a virtually identical "prior authorization program" adopted by Florida. As it does here, PhRMA argued in *Medows* that permitting a State to impose a Medicaid prior authorization

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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.

requirement on the drugs of any manufacturer that refuses to pay supplemental rebates would effectively write § 1927(d)(4) out of the Medicaid statute. The Eleventh Circuit avoided that argument by claiming that an essential ingredient of any Medicaid "formulary" is a reservation by the State of the authority to deny coverage for a drug not included in the formulary *regardless* how insistent the patient's physician may be that the patient's survival depends on access to the drug. *Medows,* 304 F.3d at 1211.[7] The court concluded that the Florida program was not a "formulary" because (it concluded) Florida at the end of the day would always acquiesce in the medical judgment of an insistent treating physician who has sought prior authorization to prescribe to one of her Medicaid patients a drug on the prior authorization list. *Id.*

The Eleventh Circuit's interpretation of § 1927(d)(4) and (5) is not tenable. It is dependent on a statutory recognition of two separate types of "prior authorization programs": (1) a "prior authorization program" of the type Michigan

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[7] While acknowledging that even a Medicaid formulary must, under § 1927(d)(4)(D), "permit coverage [of an excluded drug] . . . pursuant to a prior authorization program that is consistent with [§ 1927(d)(5)]," the appeal court "construe[d] this requirement to mean that a state must *consider* coverage for an excluded drug on a case-by-case basis." *Id.* at 1207-08 (emphasis in original). In other words, the appeals court viewed § 1927(d)(4)(D) as requiring a State that maintains a Medicaid formulary to *listen* to the entreaties of a doctor that his Medicaid patient should be given access to an excluded drug, but as granting the State absolute and final authority to overrule those entreaties.

and Florida claim to have created pursuant to § 1927(d)(5); and (2) a "prior authorization program" that must (per § 1927(d)(4)(D)) be maintained as an adjunct to any Medicaid formulary. Section 1927(d) cannot plausibly be read as contemplating these two distinct types of prior authorization programs. Indeed, § 1927(d)(4)(D) explicitly states that the "prior authorization program" that is to be maintained as an adjunct to a Medicaid formulary must be "consistent with [§ 1927(d)(5)]," which sets forth two essential attributes of every prior authorization program. Michigan and Florida claim that their programs are "prior authorization programs" of the type contemplated by § 1927(d)(5). Thus, whatever statutory requirements apply to the Michigan and Florida programs also apply to the "prior authorization program" that any State adopting a Medicaid formulary would have to maintain. In sum, the Eleventh Circuit has failed to explain how a prior authorization program of the sort maintained by Florida and Michigan can be meaningfully distinguished from the prior authorization program that must be maintained in connection with a Medicaid formulary.

Indeed, the district court in this case reviewed the Eleventh Circuit's analysis and found it unpersuasive. Slip. Op. 41. The district court stated, "The Court agrees with PhRMA that the Eleventh Circuit's interpretation of the prior authorization requirement referenced in § 1396r-8(d)(4) is not based on the

statutory text and the Court does not adopt that interpretation here." *Id.*

Instead, the district court engaged in what appears to have been at most a half-hearted effort to imbue § 1927(d)(4) with independent significance. The court stated that when a State-created formulary committee makes an adverse finding about a drug pursuant to SSA § 1927(d)(4)(C), it may "exclude" the drug from its formulary, and Medicaid reimbursement is unavailable unless prior authorization is granted; while a "prior authorization program" that conditions coverage on prior authorization cannot be said to have "excluded" the drug from any formulary. The court argued:

> Although, as PhRMA argues, there may be little difference between "conditioning" coverage on prior authorization and "excluding" a drug from coverage unless prior approval is given, there is still some difference: in the first scenario, the manufacturer's drug is on the state's list of covered drugs, but with an asterisk indicating that prior authorization is necessary; in the second scenario, the drug is not on the list at all. It is hard to fathom that, from a marketing perspective, a drug manufacturer would be indifferent between these two outcomes.

Slip Op. 42.

With all respect, *amici* believe that merely to state the district court's argument is to illustrate how insubstantial it is. The court provided no support for its position that a drug manufacturer would care which of the two scenarios a State adopted, and *amici* can think of no reason why a manufacturer would care. In

either case, the effect of the prior approval requirement is the same: imposition of the requirement will lead to a substantial reduction in the manufacturer's drug sales to Medicaid recipients within the State. Indeed, to the extent that a manufacturer did care, it would probably prefer that a State use § 1927(d)(4) to impose prior authorization requirements; at least that way, the manufacturer would have received a "written explanation" for the State's determination and thus would have some basis for contesting the determination.

While essentially conceding that the Secretary's position has written § 1927(d)(4) out of the Medicaid statute, the district court said that its holding was nonetheless mandated by the language of §§ 1927(d)(1) and (5). But as explained in Section I(A) above, those provisions can quite plausibly be interpreted in a manner that supports PhRMA's position. Thus, under *Brown & Williamson,* PhRMA's interpretation of the Medicaid statute should be adopted because it is the only one that gives substance to all provisions of the statute -- including § 1927(d)(4).

Finally, *amici* wish to add a word about the final proviso of § 1927(d)(4), which states:

> A prior authorization program established by a State under paragraph (5) is not a formulary subject to the requirements of this paragraph.

PhRMA is, of course, under the same obligation imposed on any other party promoting one interpretation of a statutory scheme whose meaning is in dispute: PhRMA needs to explain how, under its interpretation of the Medicaid statute, each provision of the statute fits into a "harmonious whole." Indeed, the district court rejected PhRMA's position in part because it viewed that position as requiring it to give no effect to the § 1927(d)(4) provisio.

Such criticism is not well taken. PhRMA's brief thoroughly explains the legislative history that led to the adoption of § 1927(d)(4) in 1993 (when Congress eased somewhat its prior ban on Medicaid formularies). PhRMA Br. 38-40. If Congress prior to 1993 banned formularies altogether yet at the same time authorized prior approval programs of some type, it cannot be the case that Congress intended (as permitted by the district court decision) that prior approval programs be made the functional equivalent of formularies. Thus, Congress must have had in mind between 1990 and 1993 a more limited definition of a permissible "prior approval program" -- and it is reasonable to conclude that Congress adopted the § 1927(d)(4) proviso in 1993 to ensure that such programs would still be permitted and would not be made subject to § 1927(d)(4)'s limitations on formularies. PhRMA has fulfilled its obligation to provide substance to the § 1927(d)(4) proviso: it has pointed to several different scenarios

under which prior approval programs were permissible during 1990-1993 and under which (by virtue of the proviso) such programs are not now subject to § 1927(d)(4)'s limitations on formularies. PhRMA Br. 34-36.[8] Thus, PhRMA's interpretation is the only one that permits the Medicaid statute to be interpreted as a "harmonious whole."

II. OPERATION OF A FORMULARY BASED PREDOMINANTLY 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 since 1990, Congress has been quite properly concerned that patient health care suffers when formularies are operated primarily on the basis of cost concerns.

Numerous studies demonstrate that basing prescription drug coverage largely on cost considerations -- as Michigan 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

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[8] Those scenarios include State-imposed limitations on the quantity per prescription or the number of refills allowed (42 U.S.C. § 1396r-8(d)(6)) and State drug use review programs, including prospective "screening for potential drug therapy problems due to therapeutic duplication, drug disease contraindication, drug-drug interactions," and for other reasons such as preventing fraud (42 U.S.C. § 1396r-8(g)).

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.

Similarly, a recent study conducted by Columbia University economist Frank Lichtenberg attests to the cost savings that result from increased use of prescription drugs, because use of new (and often more expensive) medicines tends to lower all types of non-drug medical spending. Lichtenberg found that an $18 increase in spending on new prescription drugs reduces non-drug spending by

$71.09, resulting in a net savings of $53.09. Frank Lichtenberg, "Are the Benefits of Newer Drugs Worth Their Costs? Evidence from the 1996 MEPS," 20 *Health Affairs* No. 5 (September/October 2001).

DCH insists, of course, that cost is not the *sole* criteria employed in determining which drugs are subjected to prior authorization requirements and which are not. No doubt, DCH's Pharmacy and Therapeutics Committee to a certain extent takes into account the relative efficacy of drugs within the same class in determining which drugs are deemed "preferred" and thus not subject to the prior authorization requirement. But substantial evidence before the district court (evidence that must be credited in connection with Defendants' summary judgment motion) demonstrated that the decisions of the Committee have, indeed, been driven to a great extent by cost, such that in many cases the "preferred" drugs are not the ones that the average doctor would deem most effective in treating her patient's condition. Moreover, DCH's assertion that price is not the overriding factor in determining "preferred" drug status is belied by: (1) its expectation that the Michigan Initiative will result in a $26 million annual savings in drug expenditures; (2) the evidence from other states that "prior authorization" programs have a dramatic impact on physician prescribing behavior; and (3) DCH's willingness to waive "prior authorization" requirements for *any* HHS-

approved drug whose price is lowered to DCH's satisfaction.

In light of this evidence, it is eminently reasonable to conclude that Congress does not want States to restrict Medicaid recipients' access to prescription drugs in an effort to balance State budgets. HHS abused its discretion in approving the Michigan Initiative when Michigan adopted the program as a cost-cutting measure and without following the procedures adopted by Congress to ensure that Medicaid recipients are not harmed by restrictions on their access to prescription drugs.

CONCLUSION

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

Respectfully submitted,

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September 15, 2003

CERTIFICATE OF SERVICE

I hereby certify that on this 15th day of September, two copies of the foregoing *amicus curiae* brief were deposited in the U.S. mail, with first-class postage affixed, addressed as follows:

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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 of WLF is in 14-point, proportionately spaced Times New Roman type. According to the word processing system used to prepare this brief (WordPerfect 9.0), the word count of the brief is 6,127, not including the certificate as to parties, table of contents, table of authorities, glossary, certificate of service, and this certificate of compliance.

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