STATE OF MICHIGAN
IN THE SUPREME COURT

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA,

Plaintiff-Appellant,

T.G., P.C. by her guardian and next friend, H.C., D.H., ALLIANCE FOR THE MENTALLY ILL OF MICHIGAN, MENTAL HEALTH ASSOCIATION OF MICHIGAN, MICHIGAN ASSOCIATION FOR CHILDREN WITH EMOTIONAL DISORDERS, and MICHIGAN PROTECTION AND ADVOCACY SERVICES, INC.,

Intervenors-Plaintiffs-Appellants,

v.

MICHIGAN DEPARTMENT OF COMMUNITY HEALTH,

Defendant-Appellee.

Supreme Court No. 123003

Court of Appeals No. 238862

Ingham County Circuit Court No. 01-94627-AZ

BRIEF OF WASHINGTON LEGAL FOUNDATION, ALLIED EDUCATIONAL FOUNDATION, KIDNEY CANCER ASSOCIATION, THE SENIORS COALITION, THE 60 PLUS ASSOCIATION, AND THE INTERNATIONAL PATIENT ADVOCACY ASSOCIATION AS *AMICI CURIAE* IN SUPPORT OF PLAINTIFF-APPELLANT AND INTERVENORS-APPELLANTS

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STATEMENT OF RELIEF SOUGHT

Amici curiae concur in, and hereby adopt by reference, the Statement of Relief Sought contained in the Application for Leave to Appeal.

QUESTIONS PRESENTED FOR REVIEW

1. Did the Circuit Court Abuse Its Discretion in Granting Plaintiff's Motion for a Preliminary Injunction?

- Plaintiff-Appellant answers: "No."
- Intervenors-Appellants answer: "No."
- Defendant-Appellee answers: "Yes."
- The Court of Appeals answers: "Yes."
- *Amici Curiae* Washington Legal Foundation, Allied Educational Foundation, the Kidney Cancer Association, The Seniors Coalition, The 60 Plus Association, and the International Patient Advocacy Association answer: "No."

2. Did the Legislature Grant the Department Authority to Adopt Major Changes in Medicaid and Other State Pharmaceutical Programs Without Resorting to the Constitutionally-Infirm Legislative Veto Provisions of Section 2204(1) and (3) of Public Act 60?

- Plaintiff-Appellant answers: "No."
- Intervenors-Appellants answer: "No."
- Defendant-Appellee answers: "Yes."
- The Court of Appeals answers: "Yes."
- *Amici Curiae* Washington legal Foundation, Allied Educational Foundation, the Kidney Cancer Association, The Seniors Coalition, The 60 Plus Association, and the International Patient Advocacy Association answer: "No."

INTERESTS OF *AMICI CURIAE*

The interests of *amici curiae* Washington Legal Foundation (WLF), Allied Educational Foundation, the Kidney Cancer Association, The Seniors Coalition, The 60 Plus Association, and the International Patient Advocacy Association are set forth in the accompanying motion for leave to file *amicus curiae* brief in support of Appellants.

STATEMENT OF MATERIAL PROCEEDINGS AND FACTS

In the interests of brevity, *amici curiae* hereby adopt by reference the Statement of Proceedings and Facts contained in the Application for Leave to Appeal.

In brief, Defendant-Appellee Michigan Department of Community Health (DCH) has adopted a program (the "Program") that restricts patient access to prescription drugs under the Medicaid program and several non-Medicaid programs. The Pharmaceutical Research and Manufacturers of America ("PhRMA"), along with several patient advocacy groups that intervened in the action, have challenged the Program on the ground that DCH lacks statutory authority to adopt it; they also contend that the procedures used to create the Program violate the Michigan Constitution. The Ingham County Circuit Court upheld the challenge and enjoined enforcement of the Program. The Michigan Court of Appeals reversed and remanded. PhRMA and the Intervenors seek leave to appeal.

The Program is an effort by DCH to induce doctors to prescribe lower-cost prescription and over-the-counter drugs for their state-funded patients, rather than the more-expensive drugs they would have prescribed in the absence of the Program. The Program does not absolutely preclude DCH reimbursement for these more-expensive drugs; rather, reimbursement will be denied unless the doctor obtains from DCH "prior authorization" for

use of the drugs. The parties are in considerable disagreement regarding both the number of hoops a doctor must jump through in order to obtain prior authorization and the difficulty in doing so. DCH contends that the process for obtaining prior authorization takes only a matter of minutes; PhRMA and Intervenors contend that the process is far more cumbersome, and they point out that there is no assurance that, at the end of the day after the treating physician has pursued all mandated appeals, DCH will defer to the physician's professional judgment that use of the more-expensive drug is medically warranted.

Several facts are *not* contested, however. First, DCH expects its "prior authorization" system to work; *i.e.*, to save large amounts of money by causing physicians to prescribe lower-cost drugs that they would not have prescribed if they were permitted to exercise their professional judgment without reference to the prior authorization system. Indeed, DCH insists that the Program will save Michigan $26 million in this fiscal year alone. DCH Opposition to Application for Leave to Appeal ("Opp. Br.") 5.

Second, the evidence indicates that "prior authorization" programs do, in fact, have their intended effect of significantly reducing patient access to more-expensive drugs. Where such programs have been adopted in other jurisdictions, prescription drugs placed on the "prior authorization" list have suffered immediate and substantial drops in market share. *See* Leave to Appeal Exhibit 6 (Winterton Aff. ¶¶ 12-13). Accordingly, despite DCH's insistence that the obstacles imposed on physicians by "prior authorization" programs are not significant, the dramatic shift in physician prescribing behavior brought about by such programs strongly suggests otherwise.

Third, DCH does not contend that prescription drugs placed on the "prior authori-

zation" list are not effective for their intended use, or even that they are less effective than drugs available under the Program without prior authorization. Indeed, a pharmaceutical manufacturer can have the prior authorization requirement removed for its product by agreeing to pay *supplemental* rebates to DCH, such that the effective price matches the lowest price charged to any customer anywhere in the United States by *any other* manufacturer for *any other* drug in the same therapeutic class. In other words, the *only* objection DCH has to drugs on the "prior authorization" list is their price; it has no objection based on effectiveness.

Fourth, DCH does not contest that, prior to 2001, it lacked legislative authority to adopt a prior authorization program for prescription drugs. Indeed, such a program was explicitly prohibited by statute. Accordingly, if (as it contends and the Court of Appeals held) DCH now possesses legislative authority to adopt a prior authorization program for prescription drugs, such authority must have been conferred by virtue of changes in Michigan law effected in 2001.

The key statutory provision in this case is Public Act 60 of 2001, by which the Michigan legislature funded medical assistance programs for Fiscal Year 2001-2002. Included within PA 60 is § 2204, which provides:

> (1) No later than September 30, 2001, the department shall submit changes to pharmacy policies for Medicaid recipients not enrolled in Medicaid HMOs to the chairpersons. These changes may reflect a composite of pharmacy best practices in use by HMOs under contract to provide managed care services to nonexempt Medicaid recipients.
>
> (2) A changed policy described in subsection (1) shall not be more restrictive than those developed for the EPIC program. In addition, this section does not authorize or allow therapeutic substitution.
>
> (3) Any changes described in subsection (1) shall become effective 30 days after the department submits these changes to the chairpersons unless 1 or both chairpersons

> disapprove of the changes. If both of the chairpersons disapprove, the changes do not become effective. If only 1 of the chairpersons disapproves, the chairpersons shall submit the changes to the speaker of the house and the majority leader of the senate, and the changes shall become effective 15 days after that submission to the speaker of the house and the majority leader of the senate unless both the speaker of the house and the majority leader of the senate disapprove.
>
> (4) As used in this section, "chairpersons" means the chairpersons of the senate and house of representatives appropriations subcommittees on community health.

At all times during the process of adopting the Program, DCH cited § 2204 as the source of its authority for establishing the Program. It stated that it was submitting its "prior authorization" Program to legislative leaders for approval in order to comply with what it deemed the requirements of § 2204. The Chairperson of the House appropriations subcommittee initially invoked § 2204(3) to block implementation of the Program. But by letter dated November 14, 2001, the House Speaker and the Senate Majority Leader ultimately approved the Program, "based on responses and assurances that we have received from the Department in regard to a number of issues of significant concern to us and to other members of the Legislature." The letter proceeded to spell out the "concerns" that had been expressed and DCH's "responses to those concerns," "[t]o ensure that there is no misunderstanding." To underscore the conditional nature of their approval, the Speaker and Majority Leader concluded their letter by stating, "If the Department believes that our understanding, in part or in whole, is not consistent with the response given by the Department, we expect the Department to delay implementation until such inconsistencies are resolved." *See* Leave to Appeal Exhibit 6(F).

The circuit court subsequently granted Plaintiff-Appellant's motion for a preliminary injunction against implementation of the Program. Leave to Appeal Exhibit 18, Transcript

("Tr.") 74-83. Citing *Blank v. Dep't of Corrections,* 462 Mich 103, 611 NW2d 396 (2000), the court struck down § 2204 of 2001 PA 60 as a violation of separation-of-powers principles embodied in the Michigan Constitution because it allowed the legislative function to be exercised by individual legislators, and because those legislators did, in fact, exercise the powers conferred by § 2204. Tr. 75-77. The court held further that the Program adopted by DCH was invalid because DCH lacked statutory authority to adopt a program that sought supplemental rebates from pharmaceutical manufacturers. Tr. 77.

DCH appealed from that decision. On January 17, 2002, a motions panel of the Court of Appeals stayed the circuit court's injunction "pending resolution of this appeal." Leave to Appeal Exhibit 20. On December 13, 2002, the Court of Appeals reversed the preliminary injunction and remanded for further proceedings. Leave to Appeal Exhibit 1. The court held that, quite apart from any authority DCH might have been granted under § 2204, DCH had "broad authority" under the Social Welfare Act (SWA), MCL 400.1 *et seq.,* "to accomplish its statutory responsibilities," and that broad authority included authority to impose supplemental rebate and prior authorization requirements. *Id.* at 4-5. In light of that holding, the court found it unnecessary to consider whether § 2204 "is unconstitutional as a violation of the separation of powers doctrine and whether the irreparable harm requirement was met." *Id.* at 7. The court went on to hold that the annual appropriations act had explicitly authorized adoption of supplemental rebate and prior authorization requirements with respect to non-Medicaid programs -- State Medical Program ("SMP"), Children's Special Health Care Services ("CSHCS"), and Elder Prescription Insurance Coverage ("EPIC"). *Id.* at 5-6.

ARGUMENT -- REASONS FOR GRANTING THE APPLICATION

The Application for Leave to Appeal raises issues of exceptional importance and significant public interest. Michigan Supreme Court Rule 7.302(B)(2). The DCH understandably is concerned by rising Medicaid costs and has taken steps to stem that rise. However, there is considerable grounds for believing that the Program adopted by DCH is poor health-care policy. By mandating that pharmaceuticals are to be dispensed largely on the basis of cost concerns, DCH is placing in jeopardy the health of large numbers of Medicaid recipients. *Amici curiae* urge the Court to grant Appellants' Application for Leave to Appeal, in order to determine whether the legislature really intended to authorize DCH to adopt such a penny-wise-pound-foolish policy.

Leave to appeal is also warranted because the case involves a substantial question as to the validity of a legislative act and is of major significance to the State's jurisprudence. Michigan Supreme Court Rule 7.302(B)(1) and (3). As the circuit court's decision well illustrates, there is a substantial question that § 2204 of 2001 PA 60 is unconstitutional on its face as a violation of separation of powers principles. The Court of Appeals ducked that issue by finding that legislation adopted years before the enactment of § 2204 granted DCH authority to adopt the Program. But that finding is clearly erroneous; the legislature quite obviously contemplated that if DCH sought to adopt a supplemental rebate program, it should do so pursuant to the procedures set forth in § 2204. Accordingly, resolution of this case requires that the validity of § 2204 be addressed.[1]

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[1] Although *amici curiae* agree with Appellants that the Application for Leave to Appeal should also be granted with respect to the Court of Appeals' decision upholding the Program as it applies to non-Medicaid programs, this brief does not address that separate issue.

Indeed, despite DCH's insistence that § 2204 does not violate Separation of Powers provisions of the Michigan Constitution, a close reading of DCH's opposition brief makes clear that DCH makes no real attempt to defend § 2204's constitutionality. DCH Opp. Br. at 26-30. Instead, DCH insists that offending portions of § 2204 can be severed from the remainder of the statute and that the remaining portion authorize DCH to act. *Id.* That argument is without merit. Severance is not possible because no portion of § 2204 can legitimately be deemed "otherwise complete in itself." *Blank v. Dep't of Corrections*, 462 Mich 103, 123, 611 NW2d 396 (2000).

Moreover, neither the Social Welfare Act nor any other Michigan statute authorizes DCH to adopt the Program. Indeed, as a matter of historical precedent, the legislature has consistently dealt with the issue of "prior authorization" programs through its annual appropriations act. That history can have only one explanation: the legislature has not otherwise empowered DCH to impose prior authorization requirements, and it has intended to grant such authority in connection with its annual DCH appropriations acts or not at all.

I. OPERATION OF "PRIOR AUTHORIZATION" PROGRAMS BASED PRIMARILY ON COST CONSIDERATIONS IS POOR HEALTH CARE POLICY; REVIEW IS WARRANTED TO DECIDE THE IMPORTANT HEALTH-CARE ISSUE OF WHETHER SUCH PROGRAMS ARE AUTHORIZED

Through a series of laws first adopted in 1992, the Michigan legislature has reined in prescription drug "prior authorization" programs. In doing so, the legislature was quite properly concerned that patient health care suffers when pharmaceuticals are dispensed largely on the basis of cost concerns. In light of the importance of the health-care issues raised by this case, review is warranted to determine whether the Michigan legislature really intended such

an abrupt about-face in health-care policy.

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 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 the overwhelming evidence before the circuit court was that the decisions of the P&T 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. *See, e.g.,* Affidavits of Jeffrey S. Janofsky, M.D., and Richard Owen Dolinar, M.D., Leave to Appeal Exhibits 14 and 15. *Amici* note further that the P&T Committee lists generic ibuprofen as a "preferred" analgesic non-steroidal anti-inflammatory drug, while doctors overwhelmingly prescribe newer (and more expensive) drugs such as Celebrex or Vioxx, both of which are subjected to a prior authorization requirement by DCH. Moreover, DCH's assertion that price is not the overriding factor in determining "preferred" drug status is belied by: (1) its expectation that the Program 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 sum, the Michigan legislature has had sound health-care reason to deny DCH "prior

authorization" authority for prescription drugs. Leave to appeal is warranted to address the significant health-care implications of DCH's assertion that the legislature has suddenly abandoned all such concerns.

II. REVIEW IS WARRANTED TO CONSIDER A SUBSTANTIAL QUESTION REGARDING THE VALIDITY OF A LEGISLATIVE ACT: WHETHER THE PROGRAM WAS ADOPTED THROUGH AN UNCONSTITUTIONAL PROCESS AND CANNOT BE SALVAGED BY SEVERING OFFENDING PROVISIONS

Granting leave to appeal is warranted for the additional reason that the case raises a substantial question regarding the validity of a legislative act: § 2204. The unconstitutionality of § 2204 is strongly suggested by DCH's unwillingness to defend it against separation-of-powers challenges. Leave to appeal is also warranted to consider whether the Court of Appeals improperly ducked addressing the validity of § 2204.

The bedrock principle of separation of powers -- that the power of government should be divided among the executive, legislative, and judicial branches -- is enshrined in both the United States and Michigan Constitutions. That principle prohibits the legislative branch from exercising non-legislative powers (Michigan Constitution of 1963, art iii, § 2) and mandates that the legislative power be exercised by the legislature as a whole, not by individual members thereof. *See* Bill Clause (Const 1963, art 4, § 22), the Enactment Clause (Const 1963, art 4, § 26), and the Presentment Clause (Const 1963, art 4, § 33).

Appellants' Application for Leave to Appeal cogently explains why the process used to adopt the Program -- the process outlined in §§ 2204(1) and (3) -- is a clear violation of the separation of powers principle. Application for Leave to Appeal 17-25. *Amici* will not repeat that explanation here. Suffice to say, the type of "legislative veto" provision embodied by

§§ 2204(1) and (3) is precisely the type of "legislative veto" provision condemned by this Court in *Blank* as a violation of separation of powers.

Indeed, DCH makes no real attempt to defend the constitutionality of §§ 2204's legislative veto. Rather, DCH argues that the offending provisions of § 2204 can be severed from the remainder of the section, and the remaining portion of the section provide DCH with the authority it needs to adopt the Program. DCH Opp. Br. at 26-30.

DCH's severability argument is contrary to *Blank* and ignores the language of § 2204. *Blank* explained that a law cannot be saved by severing unconstitutional portions thereof if "the unconstitutional portions are so entangled with the others that they cannot be removed without adversely affecting the operation of the act." *Blank,* 462 Mich at 123. Severability is only an option if "the remainder of the act is `otherwise complete in itself and capable of being carried out without reference to the unconstitutional [section].'" *Id.* (quoting *Maki v. East Tawas*, 385 Mich 151, 159, 188 NW2d 593 (1971)).

Once the offending portions of § 2204 are excised, nothing remains of the provision that would provide any substantive authority to DCH. Section 2204(1) authorizes DCH not to *adopt* new "pharmacy policies," but rather to "submit" such policies to the chairpersons of the appropriations subcommittees on community health of both the Senate and the House of Representatives.[2] Section 2204(3) describes the process by which individual members of the

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[2] Sections 2204(1) and 2204(2) outline the subject matter of the changes that DCH is authorized to "submit" to the chairpersons for approval. The proposed changes "may reflect a composite of pharmacy best practices in use by HMOs under contract to provide managed care services to nonexempt Medicaid recipients." § 2204(1). The legislature also imposed limitations on any proposed changes: "A changed policy described in subsection (1) shall not be more restrictive than those developed for the EPIC program. In addition, this section does

legislature are permitted to approve or disapprove any change in pharmacy policy submitted under § 2204(1). Thus, once the submittal and legislative approval provisions are excised from § 2204, nothing of substance remains to be enforced. No portion of § 2204 can legitimately be deemed "otherwise complete in itself." *Blank*, 462 Mich at 123.

DCH argues that §§ 2204(1) and (2) are capable of being carried out without reference to § 2204(3), because § 2204(1) can be read as authorizing DCH to adopt changes in its pharmacy policies and then to submit those changes to the legislature "for informational purposes." DCH Opp. Br. at 28. That argument is a clear misreading of the statute. Section 2204(1) does not contemplate that any of the proposed changes that DCH is authorized to "submit" to legislators can take effect based on some authority granted to DCH; rather, § 2204 could not be clearer that changes submitted to legislators under § 2204(1) can only become effective pursuant to the procedures outlined in § 2204(3). Because even DCH is unwilling to defend the constitutional validity of those procedures, there simply is no mechanism remaining within § 2204 whereby proposed changes submitted to the legislature pursuant to § 2204(1) can take effect.[3]

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not authorize or allow therapeutic substitution." § 2204(2).

[3] DCH argues, based on post-enactment correspondence, that legislators "understood and accepted" that adoption of § 2204 would entail "changes to DCH's Medicaid pharmaceutical policies [that] included expanded prior authorization and supplemental rebates." DCH Opp. Br. at 20. DCH's assertion that the legislature "accepted" such changes is flatly contradicted by the language of § 2204, which made clear that no such proposed changes would be permitted to take effect until legislative leaders had an opportunity to review and (if they so chose) to veto those proposed changes. Moreover, the November 14, 2001 letter to DCH from the Speaker of the House and the Senate Majority Leader made clear that those officials were *not* willing to "accept[]" the Program as it was presented to them by DCH; rather, they would permit the Program to go forward *only* if DCH agreed that the Program

DCH points out that the result in *Blank* was a finding that the unconstitutional "legislative veto" provision could be severed from the remainder of the Administrative Procedures Act (APA), and that those remaining provisions could still be enforced. DCH Opp. Br. at 29-30. But that severability finding was based on circumstances far different from those present here. In particular, there was strong evidence that the legislature would have wanted the APA to remain in place even if its legislative veto provision (portions of §§ 45 and 46 of the APA) were struck down by the courts. *Blank* noted, for example, that the APA had been in existence for several years -- and had authorized agencies to adopt rules after providing notice and an opportunity for comment -- before it was amended to add the legislative veto provision. *Blank,* 462 Mich at 124. The Court deemed that prior existence of rule-making authority "significant" in its determination that the legislature had intended to permit the severability of the remainder of the APA and to keep those remaining provisions in place should the legislative veto provisions be struck down. *Id.* In contrast, the legislature's grant of authority to DCH to "submit" changes in pharmacy policy to the legislature was simultaneous with its adoption of the legislative veto provisions of § 2204(3). Accordingly, unlike in *Blank,* there can be no basis for inferring that the legislature intended that DCH's authority to *submit* changes be transformed into an authority to *adopt* changes in the event that the legislative veto provisions of § 2204 were struck down by a court.

In sum, leave to appeal is warranted because § 2204 provides DCH with no authority to adopt the Program. Accordingly, DCH lacks authority to adopt the Program unless it can

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would be subject to the conditions set forth in the letter. Leave to Appeal Exhibit 6(F), at 2.

point to some other source of such authority. As demonstrated below, the Court of Appeals's efforts to identify alternative sources of authority are unavailing.

III. REVIEW IS WARRANTED TO CONSIDER WHETHER EITHER THE SOCIAL WELFARE ACT OR ANY OTHER STATUTE AUTHORIZES DCH TO ADOPT THE PROGRAM

At no time prior to initiation of this lawsuit did DCH ever contend that the Michigan legislature, before adopting § 2204 of 2001 PA 60, had granted it authority to inject a prior authorization requirement into its medical assistance programs as a means of inducing pharmaceutical manufacturers to pay supplemental rebates beyond those previously mandated by the federal Medicaid program. Indeed, in its public pronouncements with respect to the Program before this suit was filed, DCH stated that it was the legislature's adoption of § 2204 that empowered it to implement the Program. For example, in its September 28, 2001 letter to the chairpersons of the legislative subcommittees on community health, DCH stated explicitly, "The passage of PA 60 of 2001 has provided the state with the opportunity to change pharmacy policies within the Michigan Department of Community Health which will have the effect of reducing pharmaceutical costs to state funded programs." *See* Leave to Appeal Exhibit 6(D).

Only after this suit was filed did DCH begin asserting for the first time that, quite apart from § 2204, the legislature had previously granted it authority to adopt the Program. *See, e.g.,* Opp. Br. at 12-18. Given the litigation-driven nature of DCH's assertion, the Court should review it with a jaundiced eye.

The alleged source of DCH's prior authority (identified by both DCH and the Court of Appeals) is the Social Welfare Act ("SWA"), MCL 400.1 *et seq*. DCH and the Court of Appeals are correct that the SWA authorizes the executive branch to conduct a variety of social

service programs, including Medicaid and other medical assistance programs. They are also correct that the executive branch has assigned those administrative duties to DCH. But the SWA contains virtually no specifics regarding the executive branch's operation of Medicaid and other medical assistance programs, and is silent regarding imposition of prior authorization and supplemental rebate requirements upon pharmaceutical manufacturers. Most importantly, the SWA makes clear that social service agencies are not, in general, to look for their marching orders in the text of the SWA; rather, the more detailed directives are to come from annual appropriations bills:

> This act shall be read in conjunction with the annual appropriation act appropriating funds for the family independence agency for each fiscal year. The annual appropriation act shall be considered as a time-limited addendum to this act.

MCL 400.1b(1).

As a matter of historical precedent, the legislature has consistently dealt with the issue of "prior authorization" programs through its annual appropriations acts. For example, beginning in the 1980s and continuing through 1991, the legislature's annual appropriations act for DCH included a provision granting DCH express authority to impose prior authorization requirements on drugs purchased under the Medicaid program. *See, e.g.,* 1988 PA 322, § 1605; 1989 PA 42, § 1205; 1990 PA 11, § 911. DCH's reading of the SWA cannot be squared with the legislature's decision to include such express grants of authority in its annual appropriations acts; had the legislature really believed that it had granted DCH the authority to impose prior authorization requirements when it adopted the SWA, it would have had no need to include an identical grant of authority in the appropriations acts as well.

Between 1991 and 2000, the annual appropriations acts for DCH included a provision

that, except under very narrow circumstances, *prohibited* DCH from subjecting prescription drugs to prior authorization. 1992 PA 168, § 925; 1993 PA 186, § 919; 1994 PA 291, § 717; 1995 PA 156, § 715; 1996 PA 352, § 1612; 1997 PA 94, § 1612; 1998 PA 336, § 1612; 1999 PA 114, § 1612; 2000 PA 296, § 1612. The legislature's unbroken 1988-2000 history of always addressing DCH's "prior authorization" authority in its annual DCH appropriations act can have only one explanation: the legislature had not otherwise empowered DCH to impose prior authorization requirements, and such authority would be granted in connection with the annual DCH appropriations act or not at all.

Moreover, as noted above, entering its most recent fiscal year, DCH had been explicitly prohibited from imposing prior authorization requirements on prescription drugs. 2000 PA 296, § 1612. Thus, it is against that backdrop that 2001 PA 60, § 2204 needs to be evaluated. DCH would have this Court believe that, when the legislature adopted § 2204, it intended to leave DCH free to impose "prior authorization" requirements, subject only to whatever limitations § 2204 might have imposed on DCH's discretion. In light of the backdrop described above, *amici* respectfully submit that the legislature had *precisely the opposite* intent: the legislature intended to continue in place its decade-long ban on "prior authorization" requirements, except to the limited extent that such requirements could be imposed pursuant to the procedures outlined in § 2204. Indeed, the term "prior authorization" is not even mentioned in § 2204; it is simply not plausible that the legislature intended *sub silentio* to completely abandon its decade-long aversion to prior authorization requirements. Thus, the unconstitutionality of the procedures outlined in § 2204(3) for adopting changes to pharmacy policies forecloses the only avenue arguably provided by the legislature for imposing

prior authorization requirements.

The fundamental rule of statutory construction is to ascertain and to give effect to the legislature's intent. *Koontz v. Ameritech Services, Inc.*, 466 Mich 304, 312, 645 NW2d 34 (2002); *Production Credit Assoc. of Lansing v. Dep't of Treasury,* 404 Mich 301, 311, 273 NW2d 10 (1978). In attempting to discern whether the Michigan legislature intended to permit DCH to adopt supplemental rebate and prior authorization regulations, the Court of Appeals looked solely to the language of the SWA and deemed itself at liberty to ignore § 2204. That approach to statutory construction was clear error. In ascertaining legislative intent, a reviewing court should examine the *entire* legislative framework -- not just a portion thereof -- and attempt to give meaning to all relevant statutory provisions:

> [R]ules of statutory construction require that separate provisions of a statute, where possible, should be read as being a consistent whole, with effect given to each provision. [Citations omitted.] Also, where a statute contains a general provision and a specific provision, the specific provision controls.

Gebhardt v. O'Rourke, 444 Mich 535, 542-43, 510 NW2d 900 (1994). *See also Koontz,* 466 Mich at 312 ("Courts must give effect to every word, phrase, and clause in a statute, and must avoid an interpretation that would render any part of the statute surplusage or nugatory."); *Wickens v. Oakwood Healthcare System,* 465 Mich 53, 60, 631 NW2d 686 (2001) (same). Contrary to that rule of statutory construction, the Court of Appeals essentially deprived § 2204 of all meaning by decreeing that DCH was empowered (under the SWA) to adopt prior authorization requirements without regard to the restrictions on program changes outlined in § 2204(3). That interpretation of legislative is particularly doubtful when one considers that: (1) adoption of prior authorization requirements was precisely the type of programmatic

change the legislature had in mind when it enacted the § 2204(3) review procedures; (2) all agree that (pursuant to prior appropriations bills and notwithstanding the SWA) the legislature had explicitly prohibited prior authorization requirements before 2001; and (3) if the appeals court had deemed the SWA to conflict in any way with § 2204 concerning DCH's authority to adopt prior authorization requirements, it should have given precedence to the latter statute as the one more specifically addressing the issue of alterations of existing program requirements.[4]

DCH cites several court decisions to support its position that it possesses statutory authority -- independent of § 2204 -- to impose prior authorization requirements on prescription drug purchases. Those citations are mystifying. For example, *Anderson v. Dep't of Social Services*, 101 Mich App 488, 300 NW2d 921 (1980), has no relevance to the issues raised by this case. *Anderson* determined that dental services provided to low-income individuals by Michigan satisfied federal Medicaid requirements. The case has nothing whatsoever to do with the scope of DCH's authority under state law and nowhere touches upon the subject of "prior authorization" requirements. DCH also suggests that *federal* law authorized it to adopt the Program. DCH Opposition 15-16.[5] Any such suggestion is without merit. The issue raised by the Application for Leave to Appeal is whether the *Michigan*

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[4] This analysis is not altered by the fact that § 2204(3) appears to be unconstitutional because it incorporates a legislative veto. Notwithstanding its unconstitutionality, § 2204 nonetheless provides a strong indication that, contrary to the Court of Appeals's holding, the legislature did *not* intend to grant DCH unfettered authority to adopt supplemental rebate and prior authorization requirements.

[5] Whether the Program violates federal law is the subject of separate litigation pending in federal court. *See Pharmaceutical Research and Manufacturers of America v. Thompson*, No. 02-CV-1306 (D.D.C., filed June 28, 2002).

legislature has authorized DCH to adopt supplemental rebate and prior authorization requirements; federal law does not, indeed *cannot*, speak to that issue.

In sum, DCH can point to no law, other than § 2204, that grants it authority to impose prior authorization requirements on prescription drug sales. In the absence of such authority, DCH's actions violate Michigan law. *In re Quality of Service Standards for Regulated Telecommunications Services,* 204 Mich App 607, 611, 516 NW2d 142, 144 (1994). Review of the Court of Appeals decision is warranted to determine whether DCH has adopted policy on an important health-care issue without legislative authorization.

RELIEF REQUESTED

Amici curiae respectfully request that Appellants' Application for Leave to Appeal be granted.

Respectfully submitted,

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Dated: February 5, 2003

CERTIFICATE OF SERVICE

I hereby certify that on this 5th day of February, 2003, copies of the foregoing brief of *amici curiae* WLF, *et al.,* in support of Appellants' Application for Leave to Appeal were deposited in the U.S. mail, with first-class postage affixed, addressed as follows:

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