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Opinion No. 01-077

Constitutionality of HB 123/SB 019

QUESTIONS

House Bill 123/Senate Bill 019 proposes to amend Titles 47, 53, 63 and 71 of the Tennessee Code Annotated, relative to prescription drugs. This legislation would establish a new program, called the Tennessee Rx Program, and would require any drug manufacturer or labeler that sells prescription drugs in Tennessee through any publicly supported pharmaceutical assistance program, *e.g.*, the TennCare program, to enter into a rebate agreement with the Department of Health. Under this rebate program, the manufacturer or labeler would be required to make rebate payments to the state for prescription drugs which have been purchased by certain private citizens or "qualified residents." "Qualified residents" are those persons who are considered to be disadvantaged, elderly or disabled, as more specifically defined by the proposed legislation. Under the Tennessee Rx Program, such "qualified residents" are able to purchase drugs at a discounted price determined by the state.

This would be accomplished as follows: A fund, the Tennessee Rx Dedicated Fund, would be established to receive the rebate payments required of manufacturers and labelers. The Department of Health would establish discounted prices for drugs covered by such rebate agreements. Any participating retail pharmacy that sells prescription drugs covered by a rebate agreement would be required to discount the retail price of those drugs which it sold to "qualified residents." The Tennessee Rx Dedicated Fund would then be used to reimburse the retail pharmacies for the discounted prices they had provided to "qualified residents," and to reimburse the Department of Health for contracted services, administrative and associated computer costs, professional fees paid to participating retail pharmacies and other reasonable program costs.

The proposed legislation would prohibit profiteering and excessive pricing by manufacturers, distributors and labelers of prescription drugs, and would create extensive civil penalties to enforce the prohibition. The incentive to make manufacturers and labelers cooperate is that manufacturers and labelers that participate in the state's medical assistance program (TennCare) are required to participate in the drug rebate program proposed by the legislation. If they do not agree to so participate, their drugs will be placed on a special listing such that prior authorization will be required before those drugs will be approved for reimbursement under the state's medical assistance program. Prior authorization will also be required for drugs dispensed whose price is determined to be above the maximum retail prices established by the

Commissioner of Health.

Is House Bill 123/Senate Bill 019 constitutional? Specifically:

1. Is the authority given to Tennessee to regulate the revenues obtained by drug manufacturers, where the manufacturers' sales occur either inside or outside of Tennessee, enforceable?

2. Would the State's participation in the rebate program be subject to the restrictions of the Interstate Commerce Clause of the United States Constitution?

3. Does the proposed legislation conflict with the federal Medicaid program so that it is preempted by virtue of the Supremacy Clause?

OPINIONS

1-2. We do not have information about the location -- inside Tennessee or outside Tennessee -- of drug manufacturers and their wholesalers and distributors who would be governed by the legislation. Nor do we have information as to where sales from the manufacturers would occur. In accordance with a recent decision of the District Court for the District of Maine concerning identical legislative provisions and the precedents cited in the court's opinion, however, to the extent that out-of-state drug manufacturers' sales occur outside of Tennessee, it is our opinion that Tennessee may not constitutionally regulate the revenues obtained by the manufacturers.

Furthermore, this Office cannot answer your questions about the applicability and validity of the rebate program proposed by the Tennessee Rx Program legislation under the Commerce Clause with any degree of certainty whatsoever. The one federal court which has been presented with the issues has determined that such rebate provisions violate the dormant Commerce Clause, and are thus unconstitutional. Maine has appealed this decision, and its arguments on appeal may have some merit. However, we cannot predict the First Circuit Court of Appeal's view of such arguments. And while the future decision of the appellate court in the Maine litigation should provide some better guidance as to how one such court would judge the rebate provisions, it will not, nevertheless, establish binding precedent for the Sixth Circuit Court of Appeals, which would likely be the appellate court which would determine challenges to the Tennessee Rx Program. At this time, then, we conclude that there are constitutional impediments to the rebate provisions contained in the proposed Tennessee legislation.

3. In the Maine litigation concerning identical provisions of the Maine Act, the district court, while finding no express preemption language precluding what Maine had attempted, nonetheless determined that imposing prior authorization requirements on nonparticipating manufacturers conflicted with the goals of Medicaid, and thus violated the Supremacy Clause of the U.S. Constitution. This is so, said the court, because no Medicaid purpose is advanced by requiring approval of the Medicaid administrator before a drug is dispensed to a Medicaid recipient. Additionally, the court found conflict between the Rx

Program statutes and the federal Medicaid Act by construing the latter as prohibiting a state from imposing prior authorizations if the motivation for doing so were based solely on the refusal of a manufacturer to participate in the Rx Program.

It can certainly be argued that the Maine district court erred in these determinations. The federal Medicaid statute itself provides the states with broad discretion to subject any drug to a prior authorization requirement, 42 U.S.C. § 1396r-8(d)(1)(A), and the Rx Program prior authorization provisions might be read as merely an exercise of that discretion. Read in this way, harmony, rather than conflict, would exist between the Rx Program and federal Medicaid requirements. Moreover, no motivation test exists in the Medicaid program, and the Rx Program legislation as written would not permit the imposition of prior authorization if to do so would deprive Medicaid recipients of the drugs they need.

However, in view of the decision of the Maine district court, identical prior authorization requirements contained in the proposed Tennessee Rx Program legislation must be considered constitutionally suspect at present.

ANALYSIS

The proposed legislation which has been introduced as House Bill 123/Senate Bill 019 is virtually identical to legislation enacted by the State of Maine in 2000. The Maine legislation, entitled "Act to Establish Fairer Pricing for Prescription Drugs," created the "Maine Rx program." The profiteering, rebate and prior authorization provisions contained in the Tennessee bills, and about which you inquire, are identical to those contained in the Maine Act.

On October 26, 2000, pursuant to litigation initiated by a trade association representing drug manufacturers, the District Court for the District of Maine entered an order which preliminarily enjoined enforcement of certain challenged provisions of the Maine Act. It determined that the plaintiff pharmaceutical association had demonstrated a likelihood of success in its contentions that the prohibition on unconscionable prices and unreasonable profits and the rebate program established by the Maine Act violated the "dormant" Commerce Clause and Supremacy Clause of the United States Constitution.

The State of Maine has appealed the district court's ruling[1] as to the rebate program, including its prior authorization provisions, to the United States Court of Appeals for the First Circuit.[2] We understand that a decision could be issued at any time. If Tennessee were to enact the proposed legislation establishing

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[1]The appellate case is entitled *Pharmaceutical Research and Manufacturers of America v. Concannon, et al.* It is docketed in the First Circuit Court of Appeals as No. 00-2446.

[2]This Office is grateful to Andrew S. Hagler and John R. Brautigam, Assistant Attorneys General for the State of Maine, who are prosecuting Maine's appeal and gladly provided us with a copy of their appellate brief. We have relied heavily upon their well-researched and well-written brief in preparing this opinion.

the Tennessee Rx Program, it is likely that it would be challenged upon the same or similar legal grounds which have been asserted in the Maine litigation. A Tennessee federal court, and, on appeal, the Sixth Circuit Court of Appeals in Cincinnati, would undoubtedly examine decision(s) arising out of the Maine litigation very closely, and might well rely upon the analysis and reasoning contained therein. It is thus important to examine the recent decision issued by the Maine district court.

1-2. You have asked whether the authority given to Tennessee by the proposed legislation to regulate the revenues obtained by drug manufacturers, where the manufacturers' sales would occur either inside or outside of Tennessee, would be enforceable. Answering this question requires consideration of the Commerce Clause of the United States Constitution. Your second question inquires directly about the Commerce Clause, asking whether Tennessee's participation in the rebate program would be subject to the restrictions thereof.

The so-called "dormant" Commerce Clause doctrine has been recognized by the U.S. Supreme Court in order to limit the states' power to impinge on Congress' express Constitutional authority to regulate interstate commerce. U.S. Const. Art. I, § 8, cl. 3 ("Congress shall have the power . . . to regulate Commerce with foreign nations and among the several States.") The doctrine evolved to protect the national economy from "economic retaliation" between the separate states and to control their "mutual jealousies and aggressions." *Baldwin v. G.A.F. Seelig, Inc.*, 294 U.S. 511, 522, 55 S.Ct. 497, 500, 79 L.Ed. 1032 (1935)(citation omitted); *see also Gibbons v. Ogden*, 22 U.S. (9 Wheat.) 1, 199-200, 6 L.Ed. 23 (Marshall, C.J.)(1824)("When a State proceeds to regulate commerce . . . among the several States, it is . . . doing the very thing which Congress is authorized to do").

In the Maine litigation, the plaintiff drug manufacturers association challenged the provisions of the Maine statutes which make it "illegal profiteering" for a manufacturer to "exact [] or demand[] an unconscionable price" or to "exact[] or demand[] prices or terms that lead to any unjust or unreasonable profit." 22 M.R.S.A. § 2697(2). As the majority of the sales of the manufacturers represented by the plaintiff occur outside of Maine, the plaintiffs contended that Maine has no authority under the Commerce Clause to regulate the revenues obtained by such manufacturers. The plaintiffs also challenged the rebate program established by the Maine Act under the Commerce Clause, contending that, by virtue of the legislation, Maine had intruded impermissibly upon Congressional power to regulate interstate commerce.

In the Maine litigation, it was undisputed that all the drug manufacturers represented by the plaintiff association are located outside the State of Maine, and that by far the greater bulk of their customers--wholesalers and distributors--are likewise outside Maine. Under the contracts between these companies, the sale from the manufacturer always occurs at the place of business outside Maine, with one exception. The Maine district court held that, where the manufacturers' sales occur outside of Maine, that state has no authority to regulate the revenues obtained by the manufacturers. Order on Motion for Preliminary Injunction, p. 4. The Court thus issued a preliminary injunction which enjoined the Maine Attorney General from enforcing the portion of the Maine Rx Act which prohibits profiteering in prescription drugs in

transactions occurring outside of the State of Maine. The Court noted that this ruling was based upon "bedrock principles concerning the territorial limits of a state's power established by the Supreme Court at least as far back as 1935," citing *Baldwin v. G.A.F. Seelig, Inc., supra*; *Healy v. Beer Institute*, 491 U.S. 324, 109 S.Ct. 2491, 105 L.Ed.2d 275 (1989); *Brown-Forman Distillers Corp. v. New York State Liquor Auth.*, 476 U.S. 573, 106 S.Ct. 2080, 90 L.Ed.2d 552 (1986); and other Supreme Court decisions. Order, p. 8. In *Healy*, the Supreme Court summarized this body of law as follows:

> Taken together, our cases concerning the extraterritorial effects of state economic regulation stand at a minimum for the following propositions: First, the "Commerce Clause . . . precludes the application of a state statute to commerce that takes place wholly outside of the state's borders, whether or not the commerce has effects within the State," . . .. Second, a statute that directly controls commerce occurring wholly outside the boundaries of a State exceeds the inherent limits of the enacting State's authority and is invalid regardless of whether the statute's extraterritorial reach was intended by the legislature. The critical inquiry is whether the practical effect of the regulation is to control conduct beyond the boundaries of the State.

491 U.S. at 336, 109 S.Ct. at 2499 (internal citations omitted). The State of Maine has not appealed this aspect of the district court's preliminary injunction.

Concerning the proposed Tennessee legislation, we do not have information about the location--inside Tennessee or outside Tennessee-- of drug manufacturers and their wholesalers and distributors who would be governed by the legislation. Nor do we have information as to where sales from the manufacturers would occur. In accordance with the decision of the Maine district court and the precedents cited in its opinion, however, to the extent that out-of-state drug manufacturers' sales occur outside of Tennessee, it is our opinion that Tennessee may not constitutionally regulate the revenues obtained by the manufacturers.

The Maine plaintiffs also challenged the rebate provisions of the Maine Rx Program legislation under the dormant Commerce Clause. Determining that the rebate provisions, like the profiteering provisions discussed above, would place Maine in the position of regulating the price of out-of-state transactions between drug manufacturers and distributors, the Maine district court held that the rebate provisions violate the dormant Commerce Clause. Order, pp. 9-10.

On appeal, Maine contends that the Court's determinations concerning the rebate provisions were in error. First, it argues that Maine acts as a "market participant" in the rebate program and is therefore excepted from Commerce Clause restrictions. This well-recognized exception to the dormant Commerce Clause applies when a state seeks to obtain benefits for its citizens using its power as a buyer or seller rather than its regulatory authority. *White v. Massachusetts Council of Construction Employers, Inc.*,

460 U.S. 204, 103 S.Ct. 1042, 75 L.Ed.2d 1 (1983). Maine argues that, as the Maine Rx Program relies exclusively on the state's buying power in the market for prescription drugs,[3] Maine acts as a market participant in the rebate program, and the program is therefore not subject to Commerce Clause scrutiny.

Maine made these arguments in the district court, but they were unsuccessful. While the court recognized that the Maine Rx Program relies only upon Maine's power as the administrator of the state's Medicaid Program, it disagreed that this is an exercise of the "kind of market participation that the Supreme Court has freed from interstate commerce power limits." Order, p. 7. Relying on *South-Central Timber Dev., Inc. v. Wunnicke*, 467 U.S. 82, 104 S.Ct. 2237, 81 L.Ed.2d 71 (1984)[4], the district court ruled, instead, that the Supreme Court has limited the market participant doctrine to situations in which a state is a participant in the actual transaction at issue, and that here, Maine is not favoring its citizens in the actual transaction (the rebate program) when it buys prescription drugs in the Medicaid program. Order, pp. 6-7.

On appeal, Maine contends that *South-Central Timber Dev.* does not require the result reached by the district court. Maine points instead to the Supreme Court's decision in *White v. Massachusetts Council of Construction Employers, Inc., supra*, and argues that it is the controlling precedent. In *White*, the Court upheld a Boston regulation that relied on the city's purchasing power in the market for building construction to influence hiring decisions in a different market -- the market for construction labor. The regulation prohibited the city from entering into building contracts with contractors who would not agree to hire at least 50 percent of their workers from the local labor pool. The Court held that the Commerce Clause imposes no barrier to such an arrangement because Boston was simply using its power as a purchaser. 460 U.S. at 210, 103 S.Ct. at 1046. Maine contends that, in the Maine Rx Program, it seeks to use its purchasing power in the prescription drug market just as Boston used its purchasing power in the construction market in *White*. According to Maine, it is irrelevant that the Maine Rx beneficiaries are not "in the [Medicaid] transaction," because it was of no import in *White* that the workers were not a party to Boston's construction contracts. Arguing that nothing in the leading cases limits the market participant exception to benefits sought "in the transaction," Maine submits that *White* makes clear that the exception may be broadly applied even when the state uses its market power to do much more than simply get better terms in the purchase transaction. Rather, a state may "impose restrictions that reach beyond the immediate parties with which the government transacts business . . . [because] the Commerce Clause does not require the [state] to stop at the boundary of formal privity of contract." *White*, 460 U.S. at 211 n.7, 103 S.Ct. at 1046 n.7. As the Court later explained, it did not place a formalistic boundary on the

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[3]Maine spent over $135 million to purchase prescription drugs for its Medicaid program in 1999. The Maine Rx Program seeks to use that spending power to leverage benefits for residents who otherwise lack insurance coverage for prescription drugs.

[4]*South-Central Timber Dev.* involved a challenge to an Alaska requirement that purchasers of state-owned timber must further process the timber before shipping it out of state. A plurality of the Supreme Court determined that the market participant exception did not apply when the state, acting as a seller of goods, attempts to restrict the purchaser's further handling of those goods in its subsequent business dealings. 467 U.S. at 96-98, 104 S.Ct. at 2245-2246.

exception in *White* because "everyone affected by [Boston's regulation] was, in a substantial if informal sense, working for the city. *South-Central Timber Dev., Inc., supra*, 467 U.S. at 95, 104 S.Ct. at 2244. According to Maine, because all the prescription drugs consumed through the Maine Rx Program and Medicaid are "in a substantial but informal sense" for the benefit of the same population – Maine residents without private insurance – the fact that Maine does not purchase the drugs in the Maine Rx Program is no more significant than the fact that Boston did not hire the laborers in *White*.

Even if, as found by the Maine district court, the Rx Program were to be deemed a regulation rather than an exempt exercise of the state's purchasing power, Maine contends on appeal that the program is not likely to be found to violate the Commerce Clause. First, it argues that, unlike a wide variety of price affirmation and control statutes tried by other states and struck down by the courts, the Rx Program simply does not "regulate" interstate commerce, and thus does not run afoul of the Commerce Clause. It does not dictate the terms at which products are sold in interstate commerce, does not prohibit sales in the state, does not impose a tariff on imports into the state or tie prices in Maine to out-of-state prices. The statute's only extraterritorial aspect is that rebates are required of manufacturers who happen to be located out-of-state. The rebate requirement would apply on the same terms to any in-state manufacturer.

Second, according to Maine, the district court erred in applying the Supreme Court's price-control line of cases to the Rx Program. Each of these cases involved a state statute which explicitly tied the prices charged in one state to those in other states in order to leverage lower prices in the first state at the expense of the buyers and sellers in the other states and the market advantages they enjoyed. *See Baldwin v. G.A.F. Seelig, Inc.*, 294 U.S. 511, 55 S.Ct. 497, 79 L.Ed. 1032 (1935)(New York Milk Control Act prohibited the sale in New York of "milk produced outside of the state" if that milk was purchased at a price lower than that of milk produced within the state); *Brown-Forman Distillers Corp. v. New York State Liquor Auth.*, 476 U.S. 573, 106 S.Ct. 2080, 90 L.Ed.2d 552 (1986)(provision of New York Alcoholic Beverage Control Law required distillers to affirm that prices to wholesalers within New York would be no higher than their prices to wholesalers "in any other state"); *Healy v. Beer Institute*, 491 U.S. 324, 109 S.Ct. 2491, 105 L.Ed.2d 275 (1989)(Connecticut's contemporaneous price affirmation statute tied beer prices in that state to the lowest price at which beer was currently offered for sale "to any wholesaler in any state bordering this state"). Maine contends that the practical, economic effect of requiring a rebate payment cannot be equated to that of mandating actual out-of-state prices; the district court erred in uncritically accepting plaintiff's characterization of the Rx Program legislation as effectively regulating "the prices paid earlier in transactions in other states." Order, p. 9.

Third, Maine argues that the district court erred when it invalidated the Rx Program on a *per se* basis. While statutes that discriminate against interstate commerce or favor in-state economic interests over out-of-state interests are generally struck down as *per se* unconstitutional without further analysis, *Brown Forman, supra*, 476 U.S. at 578-79, 106 S.Ct. at 2084, statutes that regulate evenhandedly are upheld unless the incidental effects on interstate commerce clearly outweigh the putative local benefits, *Pike v. Bruce Church, Inc.*, 397 U.S. 137, 90 S.Ct. 844, 25 L.Ed.2d 174 (1970). Maine asserts on appeal that the only "extraterritorial" aspect of the rebate program is that it does not exempt products originating in

other states from the rebate requirement. This is because the rebate is only triggered by retail sales of the manufacturers' products within Maine, by Maine pharmacists, to uninsured Maine residents, and if none of a manufacturer's products are sold in Maine the manufacturer has no obligation under the law. As the Maine district court determined that the only question in the case was "whether [a state] has the power to extend its authority to out-of-state manufacturers," found that such authority would contravene the dormant Commerce Clause, and enjoined the statute, Order, pp. 8-10, in Maine's view it unjustifiably expanded the dormant Commerce Clause into a categorical ban on extraterritorial effects. Maine argues that, to the contrary, the Supreme Court has repeatedly recognized the states' constitutional authority to regulate and otherwise burden out-of-state entities on account of the flow of their products into the state, and that dormant Commerce Clause jurisprudence simply does not support a *per se* ban on all state legislation with any extraterritorial effect. Maine cites to *Exxon Corp. v. Governor of Maryland*, 437 U.S. 117, 98 S.Ct. 2207, 57 L.Ed.2d 91, reh. denied sub nom., *Shell Oil Co. v. Governor of Maryland*, 439 U.S. 884, 99 S.Ct. 232, 58 L.Ed.2d 200 (1978) (state law upheld which would prohibit vertical ownership in the gasoline industry even though the law would have eliminated a profitable portion of the out-of-state parent companies' business), and others.

Maine asserts that if the district court had correctly applied the balancing test set forth in *Pike v. Bruce Church, Inc., supra*,[5] rather than the *per se* standard, it would not have found that plaintiff was likely to succeed on the merits of its Commerce Clause claim. Maine argues that under *Pike*, a facially nondiscriminatory regulation supported by the state's legitimate interest in lower prices, such as the Maine Rx Program, must be upheld unless "the burden imposed on such [interstate] commerce is clearly excessive in relation to the putative local benefits." 397 U.S. at 142, 90 S.Ct. at 847. Maine contends that *Pike* balancing cannot possibly weigh in favor of the manufacturers because: (1) the district court enjoined the Rx program because of its alleged extraterritorial reach and not because of any actual effect on interstate commerce; (2) the plaintiff manufacturers have not alleged that the statute will have any actual market effect such as improving or worsening the terms of manufacturers' wholesale sales or increasing or decreasing the volume of their business; and (3) the statute has an unquestioned public health goal of ensuring that Maine residents receive the medications their doctors prescribe.

Maine notes, on appeal, that it has found no case in the *Pike* line of cases (or the *Brown-Forman* line) analyzing a non-discriminatory state rebate requirement such as Maine's. This is because the rebate program's unique approach does not fit easily into any existing dormant Commerce Clause rubric. For the same reason, this Office cannot answer your questions about the applicability and validity of the identical rebate program proposed by the Tennessee Rx Program legislation under the Commerce Clause with any degree of certainty whatsoever. We can say that the one federal court which has been presented with the issues has determined that the rebate provisions violate the dormant Commerce Clause, and are thus

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[5]Maine notes that courts have required *Pike* balancing even for statutes with as direct and immediate an effect on interstate commerce as an outright ban, citing *Cotto Waxo Co. v. Williams*, 46 F.3d 790 (8th Cir. 1995)(outright ban on the goods of an out-of-state manufacturer); *State of New York v. Brown*, 721 F. Supp. 629 (D.N.J. 1989)(prohibition on the sale of certain milk produced out-of-state).

unconstitutional. Maine has appealed this decision, and its arguments on appeal may have some merit. However, we cannot predict the First Circuit Court of Appeal's view of such arguments. And while the future decision of the appellate court in the Maine litigation should provide some better guidance as to how one such court would judge the rebate provisions, it will not, nevertheless, establish binding precedent for the Sixth Circuit Court of Appeals, which would likely be the appellate court which would determine challenges to the Tennessee Rx Program. At this time, then, we conclude that there are constitutional impediments to the rebate provisions contained in the proposed Tennessee legislation.

3. The Maine plaintiffs also challenged the statutory provisions which instruct the state to publicly identify those manufacturers that refuse to participate in the Maine Rx Program, and to "impose prior authorization requirements in the Medicaid program . . . as permitted by law, for the dispensing of prescription drugs provided by those manufacturers." 22 M.R.S.A. § 2681(7). If a drug is subjected to a "prior authorization requirement," the Medicaid administrator must give its approval before that drug may be dispensed to a Medicaid recipient. The plaintiffs contended that placing a drug on a prior authorization list is generally detrimental to the sales of that drug, as physicians would shift their prescribing behavior towards equivalent drugs not subject to prior authorization. Plaintiffs claimed that the prior authorization provisions conflict with the purposes of, and are preempted by, the federal Medicaid statute.

Under Article VI of the United States Constitution, the laws of the United States made in pursuance of the U.S. Constitution are "the supreme Law of the Land, and the Judges in every State shall be bound thereby. . .." However, courts must apply a strong presumption against federal preemption of state statutes, especially where a state has acted to protect the health and safety of its citizens. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 116 S.Ct. 2240, 135 L.Ed.2d 700 (1996). The first question in any preemption analysis is whether Congress has expressly stated an intention to preempt state action. *Pacific Gas & Elec. Co. v. State Energy Resources Conservation & Development Comm'n.*, 461 U.S. 190, 203, 103 S.Ct. 1713, 1722, 75 L.Ed.2d 752 (1983). Where Congress has not expressly preempted state action, an intent to preempt may be implied, but only in certain well established circumstances. A state law may be preempted for actually conflicting with the purposes of a federal Act, but "[a]ny conflict must be irreconcilable.... The existence of a hypothetical or potential conflict is insufficient." *Gade v. Nat'l. Solid Waste Mgt. Ass'n.*, 505 U.S. 88, 110, 112 S.Ct. 2374, 2389, 120 L.Ed.2d 73 (1992)(Kennedy, J., concurring).

In considering the plaintiffs' Supremacy Clause challenge, the Maine district court, while finding no express preemption language precluding what Maine had attempted, nonetheless determined that imposing prior authorization requirements on nonparticipating manufacturers conflicted with the goals of Medicaid. This is so, said the court, because no Medicaid purpose is advanced by requiring approval of the Medicaid administrator before a drug is dispensed to a Medicaid recipient. Additionally, the court found conflict between the Rx Program statutes and the federal Medicaid Act by construing the latter as prohibiting a state from imposing prior authorizations if the motivation for doing so were based solely on the refusal of a manufacturer to participate in the Rx Program. Order, pp. 11-13.

It can certainly be argued that the Maine district court erred in these determinations, and the Maine Attorney General's office has so argued on appeal. The federal Medicaid statute itself provides the states with broad discretion to subject any drug to a prior authorization requirement, 42 U.S.C. § 1396r-8(d)(1)(A), and the Rx Program prior authorization provisions might be read as merely an exercise of that discretion. Read in this way, harmony, rather than conflict, would exist between the Rx Program and federal Medicaid requirements. Moreover, no motivation test exists in the Medicaid program, and the Rx Program legislation as written would not permit the imposition of prior authorization if to do so would deprive Medicaid recipients of the drugs they need. Thus, it is arguable that the Maine district court erred in finding that the prior authorization requirements of the Rx Program are preempted by the federal Medicaid Act.

However, in view of the decision of the Maine district court, identical prior authorization requirements contained in the proposed Tennessee Rx Program legislation must be considered constitutionally suspect at present.

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