PRESCRIPTION DRUG PRICING: CONSTITUTIONAL BOUNDARIES ON STATE LEGISLATION

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MEMORANDUM

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Re: Legal Analysis of Prescription Drug Proposals

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OVERVIEW AND SUMMARY

This memorandum seeks to present to the Committee the legal principles necessary to fashion and evaluate methods of regulating the price of pharmaceuticals in Vermont. The memorandum integrates legal material presented to the Committee in past meetings with additional research.

The document has two main Parts:

Part One: **Legal Analysis**

Part Two: **Application of Legal Principles to Legislative Proposals**

Part One explains each relevant constitutional provision and discusses how it might apply to various generic types of state regulation of the prescription drug industry. Part Two then applies the legal principles described in Part Two to more specific proposals under consideration in Vermont. Because Part One presents the legal principle in detail, Part Two serves more as a summary applying our legal analysis to the main generic types of proposals.

An alternative way to understand the relationship of Part One to Part Two is as follows: Part One is organized according the main clauses of the Constitution; Part Two is organized by type of proposal. Because the detailed analysis appears in Part One as part of the exposition of constitutional law, we do not repeat it in Part Two, but instead apply the principles to the specifics of each generic type of proposal. To assist readers, in Part Two we refer to the applicable analysis in Part One.

PART ONE: LEGAL PRINCIPLES

State regulation of any multistate industry must take into account various limitations imposed by the U.S. Constitution. The limitations relevant to the present inquiry come from five clauses:

- Commerce Clause
- Supremacy Clause
- Contract Clause
- Takings Clause
- Due Process Clause

I. COMMERCE CLAUSE

A. Overview

1. Introduction: The "Negative" Implications of the Commerce Clause

The Commerce Clause of the United States Constitution provides that Congress may "regulate Commerce with foreign Nations, and among the several States." Article I, ' 8, cl. 3. Since 1849, the Supreme Court has interpreted the Commerce Clause as including two features: a grant of power to Congress, and limitation on the power of states. The first feature defines the power of Congress to pass laws concerning goods or services that are in or that affect interstate commerce. Conversely, this same grant of power precludes the U.S. Congress from regulating matters that are entirely intrastate in character.

The Commerce Clause's second feature is its limitation on the power of the States to regulate interstate commerce. This feature is sometimes referred to as the "negative" or the "dormant" Commerce Clause. This document's discussion of the Commerce Clause is concerned with its negative implications.

The primary concern of the dormant Commerce Clause is to ensure that buyers and sellers have access to a national market in which they are able to transact business with out-of-state buyers and sellers free from undue interference by the states. The negative Commerce Clause protects this national market against state statutes that protect a state's own economy from out-of-state competition and inconsistent state statutes that create obstacles to national competition.

As a general rule, state regulation therefore must involve a matter not requiring uniformity among the states, and it must not unduly burden interstate commerce. When states encroach on matters requiring federal uniformity or pass laws unduly burdening interstate commerce, courts will step in and invalidate those laws. While courts generally invalidate protectionist state legislation, the courts also are mindful of the states' inherent police powers to enact legislation to promote the health and safety of their citizens.

State laws can violate the Commerce Clause in two ways.

1. State laws may discriminate against out-of-state business and in favor of in-state businesses. In general, courts apply "rigorous" or "heightened" scrutiny to such statutes. Under this test, state laws are generally "virtually per se invalid." This test is applied to statutes that discriminate between in-state businesses and out-of-state businesses or those that by their terms or in practical effect control commerce outside of the enacting state's borders. States may defend such statutes only by showing that the statute has non-protectionist justifications and is the least burdensome means to achieve the statute's purpose.

2. State laws that do not discriminate against out-of-state business in favor of in-state businesses still may impose burdens on interstate commerce disproportionate to the in-state benefits. Such laws are subject to a court's balancing of benefits and burdens.

The boundary between these two types of violation is not always clear. Courts acknowledge this fact. In evaluating a state statute, therefore, they focus on its practical effect, rather than its express terms. Moreover, the courts consider the consequences that will result if several states adopted laws similar to the law being challenged. As one court explained,

> Negatively affecting interstate commerce is not the same as discriminating against interstate commerce. In a Commerce Clause context, "discrimination" means differential treatment of in-state and out-of-state economic interests that benefits the former and burdens the latter.

Cotto Waxo v. Williams, 46 F.3d 790, 794 (8th Cir. 1995).

The remainder of this overview provides more detail on the two methods of analysis that courts apply: the "heightened scrutiny" method and the "balancing" method. It then summarizes the requirements a state law must meet in order to tax goods or services in interstate commerce and concludes by noting the effect of federal authorization of state regulation which, absent such federal authorization, would violate the Commerce Clause.

2. State Laws that Discriminate Against Interstate Commerce

State laws which are designed to protect in-state competitors from out-of-state competitors, or which have such an effect, are "virtually per se invalid." These laws are "virtually per se invalid" because the courts assess their validity under a "strict" or "rigorous" scrutiny test. For a state or local law to pass the rigorous scrutiny test, the law must promote a legitimate local purpose and there must be no nondiscriminatory means of furthering that purpose.

One of the leading cases involving a state statute protecting local business interests is Baldwin v. G.A.F. Seelig, 294 U.S. 511 (1935). In Baldwin, the Supreme Court invalidated New York's enactment of a law setting minimum wholesale prices for milk for the purpose of protecting local milk producers. The statute was challenged by a local milk dealer who had been denied a license to sell milk purchased from a Vermont dealer at a price lower than the minimum price set by the New York law. Thirty percent of the milk sold in New York came from out of state.

More recent cases reinforce the view that states may not act to protect local businesses. The Supreme Court invalidated an Ohio law making its statute of limitations inapplicable to claims against out-of-state corporations. Bendix Autolite Corp. v. Midwesco Enterprises, Inc., 486 U.S. 888 (1988). The statute forced foreign corporations to either register with the state and be subject to its general jurisdiction or be subject to suit forever. Another example of a local law held per se invalid is found in C & A Carbone, Inc. v. Town of Clarkstown, 511 U.S. 383 (1994).

Carbone involved a New York town's ordinance requiring all local waste to be processed through the local facility where haulers had to pay an above-market tipping fee. The ordinance was intended to offset the costs of building a local waste transfer facility constructed in part to comply with state environmental laws. See also Barringer v. Griffes, 1 F.3d 1331 (2nd Cir. 1993) (holding Vermont use tax on automobiles invalid because it "create[s] a bias towards in-state purchases" as a result of its failure to provide a credit for cars purchased out of state).

Just as a state law many not protect in-state businesses from out-of-state competition, a state may not regulate in a way that "hoards" a scarce in-state resource for local use. For example, the Supreme Court invalidated an Alabama law imposing a hazardous waste disposal fee on hazardous waste generated out-of-state, but not on hazardous waste generated in-state. Chemical Waste Management, Inc. v. Hunt, 504 U.S. 334 (1992). The Court observed that the state could have addressed its environmental concerns through nondiscriminatory means. See also New England Power Co. v. New Hampshire, 455 U.S. 331 (1982) (invalidating a New Hampshire law prohibiting a private power company from exporting out-of-state hydroelectric power that was generated in-state).

The leading example of a state law withstanding the rigorous scrutiny test is Maine's complete ban on importation of live bait fish; the Court found the ban was necessary to protect local fish from parasites. Maine v. Taylor, 477 U.S. 131 (1986). The state made a strong factual showing that no other means were available for protecting local fish. Maine v. Taylor may be contrasted with Dean Milk Co. v. City of Madison, 340 U.S. 349 (1951). In that case the Court concluded that the city could not enact, in the name of food safety, an ordinance requiring that milk sold within its limits be pasteurized at a local processing plant. The Court concluded there were other "reasonable nondiscriminatory alternatives, adequate to conserve legitimate local interests."

Finally, courts are skeptical of health and safety arguments when they are tied to matters relating to pricing and competition. For example, in Baldwin, the Supreme Court responded to New York's contention that its minimum price laws were necessary to protect the adequacy of a wholesome supply of milk as follows:

> Price security, we are told [by the state defending the statute], is only a special form of sanitary security; the economic motive is secondary and subordinate; the state intervenes to make its inhabitants healthy, and not to make them rich. On that assumption we are asked to say that intervention will be upheld as a valid exercise by the state of its internal police power, though there is an incidental obstruction to commerce between one state and another. This would be to eat up the rule under the guise of an exception. Economic welfare is always related to health, for there can be no health if men are starving. Let such an exception be admitted, and all that a state will have to do in times of stress and strain is to say that its farmers and merchants and workmen must be protected against competition from without, lest they go upon the poor relief lists or perish altogether. To give entrance to that excuse would be to invite a speedy end of our national solidarity.

Baldwin, 294 U.S. at 523.

3. State Laws that Do Not Discriminate Against, But Which Still Impose Burdens on, Interstate Commerce

A neutral but burdensome law is valid if the burden on interstate commerce is not disproportionate relative to the local interest the law seeks to achieve. Courts frequently quote from the Supreme Court's description of the balancing test in Pike v. Bruce Church, Inc. 397 U.S. 137, 142 (1970):

> Where the state regulates evenhandedly to effectuate a legitimate local public interest, and its effects on interstate commerce are only incidental, it will be upheld unless the burden imposed on

> such commerce is clearly excessive in relation to the putative local benefits. If a legitimate local purpose is found, then the question becomes one of degree. And the extent of the burden that will be tolerated will of course depend on the nature of the local interest involved, and on whether it could be promoted as well with a lesser impact with state activities.

In applying the balancing test, a state will have more leeway to burden interstate commerce if the purpose is to promote local health and safety. Courts will consider, however, whether means less burdensome to interstate commerce are available to promote the health or safety interest.

An example of a law upheld because the benefits of the state law involved health and safety is Sligh v. Kirkwood, 237 U.S. 52 (1915). In that case the Court upheld a Florida statute banning the sale of fruit that was immature and unfit for human consumption. The Court declared: "The power of the State to prescribe regulations which shall prevent the production within its borders of impure foods, unfit for use, and such articles as would spread disease and pestilence, is well established." 237 U.S. at 60.

On the other hand, in Pike v. Bruce Church, supra, the Court applied the balancing test to invalidate a facially nondiscriminatory statute. The Court held the negative Commerce Clause prohibited an Arizona law calling for all cantaloupes grown in the state to be packaged in the state. The law would have required the processor challenging the statute to build a $200,000 processing plant in Arizona. The state's purpose -- enhancing the reputation of its cantaloupes by prohibiting deceptive advertising on the packaging -- was insufficient to justify this burden.

Recently, in General Motors Corp. v. Tracy, 519 U.S. 278 (1997), the Court reaffirmed the notion that a state may burden interstate commerce when promoting the health and safety of its citizens. Ohio had imposed general sales and use taxes on natural gas purchases from all sellers, except regulated public utilities that met the state's statutory definition of a "natural gas company." The law was challenged by an out-of-state competitor of the public utilities. The Court declared (519 U.S. at 306 (footnotes and internal quotes omitted)):

> State regulation of natural gas sales to consumers serves important interests in health and safety in fairly obvious ways, in that requirements of dependable supply and extended credit assure that individual buyers of gas for domestic purposes are not frozen out of their houses in the cold months.

In considering the burden a state law places on interstate commerce, the Court will consider the burden created by one state's law with respect to the laws of other states. In Bibb v. Navajo Freight Lines, 359 U.S. 520 (1959), the Court addressed an Illinois truck safety law requiring "contour" mud guards for trucks operating on its roads. The law conflicted with the laws of 45 other states permitting "straight" mud guards, and it conflicted directly with an

Arkansas statute which banned contour mud flaps. The Court held the Illinois statute invalid.

That the effects of a facially neutral state law fall disproportionately on out-of-state businesses does not make the law invalid:

1. In Exxon Corp. v. Maryland, 437 U.S. 117 (1978), the Court held that Maryland could enact a law precluding producers and refiners of petroleum products from operating retail service stations within the state and requiring that producers and refiners extend all "voluntary allowances" equally to all stations they provide. The effect of the law's divestiture requirements fell entirely on out-of-state producers.

2. Similarly, in Parker v. Brown, 317 U.S. 341 (1943), the Court upheld a California regulation mandating price fixing. The California marketing scheme challenged in Parker required raisin producers to hand over two-thirds their crop to a marketing committee, which effectively set prices to prevent "injurious" competition. Most of the raisins were subsequently sold in interstate commerce.

The inner political check: A useful analytical tool in assessing the potential vulnerability to a Commerce Clause challenge of nondiscriminatory state legislation is the concept of "inner political check." If the burdens of a state regulation fall primarily out-of-state, the state's political processes provide fewer restraints on the regulatory activity, the regulation will be subject to greater judicial scrutiny. If, however, the state law is largely subject to the state's political processes, it may be more likely to withstand a court challenge. See ROTUNDA & NOWAK, TREATISE ON CONSTITUTIONAL LAW (3d Ed. 1999) ' 11.11.

4. States Laws Assessing Nondiscriminatory Taxes on Good or Services with Relations to Interstate Commerce

Because state taxation has elements in common with state price regulation, and because many cases address the constitutionality of state taxes, a discussion of major tax cases here is useful.

Courts apply a four-part test to determine whether the validity of a state tax affecting interstate commerce. Courts consider whether the tax (1) has a substantial nexus to the state (some physical presence required); (2) is fairly apportioned according to the share of activity or property that is attributable to the state; (3) discriminates against interstate commerce; and (4) is fairly related to the benefits or services provided by the state. Complete Auto Transit v. Brady, 430 U.S. 274, 279 (1977).

The Court applied the Complete Auto test to invalidate a state tax in Quill v. North Dakota, 504 U.S. 298 (1992). The Court held that a national mail order catalog business, with no significant physical presence in the taxing state, did not have a substantial nexus with the state by virtue of its flyers, catalogues, advertisements in national magazines and phone solicitations. Even though the contacts between the business and the state were sufficient to satisfy the Due Process Clause, they were insufficient to satisfy the negative Commerce Clause.

5. States Can "Violate the Commerce Clause" with Congressional Authorization

Because the Commerce Clause provides the U.S. Congress with the power to regulate interstate commerce, Congress may sanction state and local laws that would otherwise violate the Commerce Clause. In ascertaining whether Congress has authorized state lawmakers to burden interstate commerce, courts ask whether federal law clearly authorizes the state action. See, e.g., South-Central Timber Dev., Inc. v. Wunnicke, 467 U.S. 82 (1984) (plurality opinion) (holding that federal natural resources law did not clearly authorize the state to require persons buying timber from the state to process the timber in-state before exporting it).

This effect of constitutional law has a solid policy foundation: When a state acts alone, unrepresented, out-of-state interests are at risk of bearing the brunt of the regulations imposed by the state; but when Congress acts, all segments of the country are represented in its decision.

Having provided this overview, we turn now to the Commerce Clause principles implicated by five general types of state regulation now under discussion in Vermont:

- Price Regulation
- State and Local Laws that Exclude Competitors
- The "State-as-Market-Participant" Exception to the Commerce Clause
- State Regulation Incorporating Reference Prices
- Price Disclosure

B. Direct Price Regulation

The Commerce Clause implications of price regulation depend on what kinds of transactions are being regulated -- out-of-state sales or in-state sales. Each type of price regulation is discussed next.

1. Price Regulation of Out-of-State Sales

a. Overview

A state cannot constitutionally regulate a sale which occurs outside its boundaries. A court will find a statute per se unconstitutional, without further inquiry, if it determines that the statute dictates how buyers and sellers do business outside of the state. Courts often refer to such statutes as having an "extraterritorial reach."

For example, a state law requiring a producer to sell at a particular price to wholesalers which in turn sell into the regulating state would constitute an unconstitutional exertion of control over out-of-state transactions.

Two separate lines of caselaw support this conclusion: cases that directly address state pricing laws, and cases analyzing a state's jurisdiction to tax particular transactions for goods or services. These are discussed next.

b. Pricing Cases

In Baldwin v. G.A.F. Seelig, Inc., supra, the Court invalidated New York's denial of a license to sell milk to a business that purchased milk from an out-of-state producer at a lower price than the minimum price established by New York law. In a later case, the Supreme Court described the New York law it invalidated as being one that "said in effect to farmers in Vermont: your milk cannot be sold by dealers to whom you ship it in New York unless you sell it to them in Vermont at a price determined here." Henneford v. Silas Mason Co., 300 U.S. 577, 585 (1937). The Henneford Court's description of the Baldwin holding stands for the clear proposition that one state cannot set prices for transactions occurring in another state.

Tying in-state sales to out-of-state prices: The Supreme Court more recently has held invalid statutes that tie in-state sales to out-of-state prices, where the statute has the effect of determining prices in other states. In Brown-Forman Distillers Corp. v. New York State Liquor Auth., 476 U.S. 573 (1986), the Court invalidated a New York law requiring liquor producers to affirm that, during a given month, they would not sell to any customer out of New York at a lower price than the price they charged New York wholesalers. Once the producer made the affirmation, it could not lower out-of-state prices during that month without violating the New York law. The effect of this rule, said the Court, was to set a price floor in other states for the month following the producer's affirmation.

In the case of Healy v. The Beer Institute, 491 U.S. 324 (1989)(applying Brown-Forman to hold a similar law invalid), the Supreme Court provided guidance for assessing whether a statute has a per se unconstitutional extraterritorial reach or effect:

> Healy articulates a three part test for evaluating the extraterritorial effect of state regulation: 1) whether the state statute applies to commerce wholly outside the state's borders; 2) whether a statute has the "practical effect" of controlling conduct outside a state's borders; and 3) how the statute affects legitimate regulations

> imposed by other states, and what impact would be created if other states enacted similar legislation.

Federal Express Corp. v. California Pub. Util. Comm'n, 723 F. Supp. 1379, 1382-3 (D. Cal. 1989) (upholding California transportation regulations that did not apply to or control out-of-state commerce and did not conflict with regulations in other states) (emphasis added).

Given these judicial interpretations of the Commerce Clause, it is apparent that regulation of the prices of transactions occurring out-of-state would constitute an unconstitutional extraterritorial reach of state power. An attempt to regulate prices of out-of-state transactions would not withstand the 3-part test articulated by the Supreme Court in Healy: price regulation of out-of-state sales would apply to commerce wholly outside the state's borders, it would have the "practical effect" of controlling conduct beyond the borders, and it may conflict with valid regulations of the state in which the transaction does occur.

Note that Brown-Forman expands this prohibition to state laws that regulate in a manner that preclude a business from altering its prices in other states.

c. Tax Cases

A close analogy to price regulation is state taxation. Price regulation constitutes a more burdensome variation of taxation, since its effects are more difficult to pass on to others in the stream of commerce.

The Supreme Court has explained on a number of occasions that where transfer of possession from seller to buyer occurs outside the state, a state tax on the sale may be invalid under both the Due Process and the Commerce Clauses. Two early examples include McGoldrick v. Berwind-White Coal Mining Co., 309 U.S. 33 (1940), and McLeod v. J.E. Dilworth Co., 322 U.S. 327 (1944).

In McGoldrick, the Court upheld a tax on coal sales. The Court observed that the "transfer of possession to the purchaser within the state ... is the taxable event regardless of the time and place of passing title...." 309 U.S. at 49.

McLeod presents the contrasting case. There the taxpayer sold mill supplies and machinery and was headquartered in Tennessee. Its traveling salesmen obtained orders from Arkansas customers and submitted those orders to the Tennessee home office for approval. The seller transferred title and possession to the Arkansas buyer on delivery to the carrier in Tennessee. The Tennessee office made the collections. When Arkansas attempted to apply its sales tax to these sales, the Court invalidated the tax: "[For] Arkansas to impose a tax on such transactions would be to project its powers beyond its boundaries and to tax an interstate transaction." 322 U.S. at 330. See also R. ROTUNDA AND J. NOWAK, CONSTITUTIONAL LAW TREATISE ' 13.6 at 431 and n.5 (3rd Ed. 1999)("To permit a state to tax a sale consummated outside the state would violate both due process and the commerce clause.").

More recently, the Supreme Court applied Commerce Clause analysis to the more complicated situation of a sales tax assessed on mail order catalog sales. The Court determined that where a company's only contact with a state is sales by mail order, the Commerce Clause prohibits the state from imposing any tax obligation on the company. Quill Corp. v. North Dakota, 504 U.S. 298 (1992). Quill involved a North Dakota tax on a retailer of office supplies and equipment, which had no outlets and no sales representatives in North Dakota and owned no significant tangible property within the state. The retailer solicited business through catalogs and flyers, advertisements in national periodicals, and telephone calls. It delivered all of its merchandise by mail or common carrier from out-of-state locations.

As explained above, the Court in Quill found that the retailer's continuous and widespread solicitation of business within North Dakota were sufficient for the state to exercise its jurisdiction over the company without violating the Due Process Clause. However, the Court found that the state's specific requirement that the company collect a use tax from its customers violated the Commerce Clause because mail orders provided an insufficient nexus for purposes of the Commerce Clause. The Court emphasized that the retailer had no physical presence in the state. The Court left open the possibility that if the company's contacts with a state included more than mere mail order sales, the state could impose the tax obligation without violating the Commerce Clause.

Quill and the Supreme Court's earlier cases on state power to tax underscore the Commerce Clause's prohibition on state regulation of transactions occurring in other states. While McGoldrick makes clear that a state may tax a transaction where transfer of possession occurs in that state, McLeod makes clear that if title and transfer of possession occur out-of-state the state may not tax that transaction. Finally, in Quill, it appears that the transfer of possession of the goods that North Dakota sought to tax actually occurred within North Dakota, but the Supreme Court nevertheless held that the state had no jurisdiction to require Quill to collect the tax.

2. Price Regulation of In-State Sales

In contrast to price regulation of transactions occuring out-of-state, states have jurisdiction to regulate transactions occuring within the state. Quill, described immediately above, indicates that entities that have a sufficient physical presence in a state are subject to regulation by that state. Outside of the public utility context (which is special for reasons discussed in Part One: I.C.3 below), however, there are few cases addressing state power to set prices. Nevertheless, state price regulation of in-state transactions is comparable to state taxation in that both influence the price of the commodity. (Price regulation may raise other constitutional considerations, however. See Parts One: III.B, IV.D and V.C.) As a result, if a state has jurisdiction to tax, a court will likely conclude it has jurisdiction to regulate prices.

While courts are likely to find that states have jurisdiction to regulate transactions taking place within their borders, "state regulation of retail sales is not, as a constitutional matter, immune from our ordinary Commerce Clause jurisprudence." General Motors Corp., 519 U.S. at 291 n.8. So long as out-of-state competitors and in-state competitors are treated equally and have equal access to other buyers and sellers in the state, state regulation of in-state transactions may avoid analysis under the rigorous standard of review normally applied to instances of discrimination.

Nondiscriminatory price regulation of in-state sales still may be analyzed under the balancing test of Pike v. Bruce Church, Inc. See Part One: I.A.3. A reviewing court would weigh the burden price regulation has on interstate commerce against its anticipated benefits.

An example of an application of the balancing test being applied to state regulation of pharmaceutical wholesalers is Ferndale Laboratories, Inc. v. Cavendish, 79 F.3d 488 (6th Cir. 1996). Ferndale involved a Michigan pharmaceutical manufacturer's challenge to an Ohio statute requiring wholesale distributors to register with Ohio and pay a license fee. The requirement applied evenhandedly to all in-state and out-of-state wholesale distributors. The court concluded that the statute "effectuates a very strong local public interest by providing information concerning the types and sources of prescription drugs entering Ohio" and that the $100 fee and two-page registration form imposed little, if any, burden on interstate commerce.

Cotto Waxo Company v. Williams, 46 F.3d 790 (8th Cir. 1995), provides another recent, albeit contrasting, example of an application of the balancing test. At issue was a Minnesota law prohibiting the sale in the state of petroleum-based sweeping compounds. The court found that the law minimally burdened interstate commerce. The Court found no evidence, however, that the statute contributed to the state's legitimate objective of preventing contamination or promoting conservation and therefore held that a trial was necessary to determine if the state's interest in the statute was sufficiently legitimate.

The different outcomes in Ferndale and Cotto Waxo underscore the difficulty in predicting how a court may apply the balancing test to price regulation. Given the lack of precedent for state price regulation outside of the public utility context, it is difficult to predict the result of an application of the Commerce Clause balancing test to price regulation in the prescription drug area. A court would have to see a clear state policy that could not be addressed by less burdensome means.

C. State and Local Laws that Exclude Competitors

1. Overview

This section examines whether a state may, consistent with the Commerce Clause, bar in-state sales except those passing through one retail or wholesale entity. The assumption is a state law involving the use of a wholesale or retail entity -- a state program or a privately run or state-run business -- through which each retail sale must pass. All sellers, whether located in-state or out-of-state, would be limited to accessing in-state consumers except through the state regulatory regime.

States have a long history of granting exclusive franchises in the utility context, such as for electricity, gas, telephone, cable, and water. Few cases challenge the existence of these utility franchises. Outside the utility area, there is little precedent with the exception of state and local regulation of solid waste. The remainder of this section considers applicable precedent in the non-utility area and then the public utility context.

2. Non-Public Utility Context

There are few cases, outside the utility context, directly addressing a state's attempt to establish or provide entities with the exclusive right to control the flow of products into the state. This section first considers how such a state regime fits within the broader context of Commerce Clause case law, as set forth in the Commerce Clause Overview, Part One: I.A. It then considers the one area in which courts have addressed an analogous situation, restrictions on the flow of waste.

a. Early Supreme Court Precedent

The establishment of a franchise, wholesale (or retail) through which all in-state sales must pass would serve as a barrier preventing out-of-state businesses from reaching local consumers. This barrier feature would likely subject the regime to the "rigorous" scrutiny standard of Commerce Clause review and make it "virtually per se" invalid.

Baldwin v. G.A.F. Seelig addressed a New York law regulating milk prices through a regulatory regime requiring all in-state dealers to be licensed by the state. The license requirement facilitated a pricing system that protected in-state milk producers. Specifically, the program barred out-of-state businesses from access to local consumers unless the out-of-state businesses were willing to meet the state's condition of charging the higher price that protected the higher prices of in-state milk producers. The license system was challenged by a local milk dealer who had been denied a license to sell milk purchased from a Vermont dealer at a price lower than the minimum price set by the New York law. The Supreme Court said that New York could not set minimum wholesale prices for milk transferred in out-of-state transactions in order to protect local milk producers:

> New York asserts her power to outlaw milk so introduced by prohibiting its sale thereafter if the price that has been paid for it to the farmers of Vermont is less than would be owing in like circumstances to farmers in New York. The importer in that view may keep his milk or drink it, but sell it he may not. Such a power, if exerted, will set a barrier to traffic between one state and another as effective as if customs duties, equal to the price differential, had been laid upon the thing transported.

Baldwin, 294 U.S. at 521.

Aside from Baldwin, other Supreme Court decisions also have invalidated state statutes barring competitors from access to local markets. For example:

- In Buck v. Kuykendall, 267 U.S. 307 (1925), the Court addressed a state law prohibiting common carriers from using state highways over certain routes without a certificate of public convenience. The Court said the law's "primary purpose is not regulation with a view to safety or to conservation of the highways, but the prohibition of competition. It determines not the manner of use, but the persons by whom the highways may be used. It prohibits such use to some persons while permitting it to others for the same purpose and in the same manner." Id. at 315-316.

- H. P. Hood & Sons v. Du Mond, 336 U.S. 525 (1949), involved a challenge to a New York law requiring businesses distributing milk in the state to obtain a license from the Commissioner of Agriculture and Markets. The Commissioner was authorized to withhold the license unless satisfied "that the issuance of the license will not tend to a destructive competition in a market already adequately served, and that the issuance of the license will be in the public interest." A Massachusetts distributor of milk who had two receiving stations sought a license for a third station but was denied. The Court held that a state may not refuse to license an additional receiving station for milk to be shipped to a distributor from another state. It rejected the state's arguments that the law was needed to prevent milk shortages and that by reducing the amount of milk received at plants of competitors within the area their cost of handling milk would be increased.

- In Pennsylvania v. West Virginia, 262 U.S. 553 (1923), the Court invalidated a West Virginia law regulating pipe-line companies designed to keep all state-produced natural gas in the state that would be required for local needs. The Court held that the State could not accord to its own consumers a preferred right of purchase over consumers in other states. The Court observed that

> West Virginia encouraged and sanctioned the development of that part of the business and has profited greatly by it. Her present effort, rightly understood, is to subordinate that part to the local business within her borders. In other words, it is in effect an attempt to regulate the interstate business to the advantage of the local consumers. But this she may not do.

Id. at 598.

Would Baldwin apply to a state law requiring all sellers to deal only with a single state-appointed purchaser? It is possible, although the specific issue has not arisen. There are similarities and differences. Both the milk price licensing regime in Baldwin and a state-granted exclusive franchise operate to limit the access of out-of-state businesses to local consumers by channeling all imports through a single state system. In Baldwin, the system involved a licensing process requiring that the importer affirm its compliance with the New York minimum price laws for its out-of-state transactions; the establishment of an exclusive regulatory regime for sale of all of a commodity would similarly impact all importers of the commodity by precluding their market entry. In fact, one could argue that whereas Baldwin at least allowed outside sellers to enter, albeit only if they complied with the price floor, a regulatory regime requiring all of a commodity to go through a single wholesaler allows no one to enter.

b. Exclusivity and the case of Carbone

More recently, in C & A Carbone, Inc. v. Town of Clarkstown, supra, the Supreme Court directly addressed a law granting an exclusive franchise to an in-state business for waste processing.

Carbone arose as a result of the town of Clarkstown, New York's effort to build a waste transfer station. The station was built by a private contractor which agreed to build the waste transfer station and operate it for five years, and then sell it to the town for $1. To assure the station's commercial viability, the town assured the station's market: the town passed an ordinance requiring all nonhazardous waste generated or brought into the town to be processed at the transfer station, guaranteeing a minimum amount of waste would go through the station, despite its above-market fees. All recyclers, such as Carbone, had to bring nonrecycled waste to the transfer station and pay an above-market tipping fee on the waste. Carbone, a waste hauler, challenged the Clarkstown ordinance.

The Court held that the law deprived out-of-state businesses of access to a local market and was therefore virtually per se invalid under the Commerce Clause. The Court rejected the argument that the statute applies evenhandedly to all solid waste processed within the Town, regardless of point of origin. The Court said:

> By requiring Carbone to send the nonrecyclable portion of this waste to the Route 303 transfer station at an additional cost, the flow control ordinance drives up the cost for out-of-state interests to dispose of their solid waste. Furthermore, even as to waste originant in Clarkstown, <u>the ordinance prevents everyone except the favored local operator from performing the initial processing step. The ordinance thus deprives out-of-state businesses of access to a local market.</u> These economic effects are more than enough to bring the Clarkstown ordinance within the purview of the Commerce Clause. It is well settled that actions are within the domain of the Commerce Clause if they burden interstate commerce or impede its free flow.

<u>Id.</u> at 389 (emphasis added).

The Court rejected the Town's contention that the ordinance was nondiscriminatory because it also covered in-state and in-town waste processors. The Court noted that the ordinance allowed only the favored facility to process waste located within the limits of the town. The Court found this "no less discriminatory because in-state or in-town processors are also covered by the prohibition." <u>Id.</u> at 1682.

To support its holding, the <u>Carbone</u> Court cited a long string of cases invalidating protectionist state laws because they restricted the movement of articles through interstate commerce, including: <u>Dean Milk Co. v. Madison</u>, 340 U.S. 349 (1951)(striking down a city ordinance that required all milk sold in the city to be pasteurized within five miles of the city lines); <u>Minnesota v. Barber</u>, 136 U.S. 313 (1890) (striking down a Minnesota statute that required any meat sold within the state, whether originating within or without the State, to be examined by an inspector within the State); <u>Toomer v. Witsell</u>, 334 U.S. 385 (1948) (striking down a South Carolina law that required shrimp fishermen to unload, pack, and stamp their catch before shipping it to another State).

Then the Court directly addressed the <u>exclusivity aspect</u> of the Clarkstown ordinance:

> <u>The only conceivable distinction from the cases cited above is that the flow control ordinance favors a single local proprietor. But this difference just makes the protectionist effect of the ordinance more acute</u>. In <u>Dean Milk</u>, the local processing requirement at least permitted pasteurizers within five miles of the city to compete. An out-of-state pasteurizer who wanted access to that market might have built a pasteurizing facility within the radius. The flow control ordinance at issue here squelches competition in the waste-processing service altogether, leaving no room for investment from outside.

Id. at 392 (emphasis added).

After Carbone, federal courts have applied rigorous scrutiny analysis to invalidate similar waste flow control laws which established entities through which certain waste had to flow. One court described New Jersey's laws as follows:

> Like the governmental entities in the other cases involving local processing requirements, New Jersey is regulating a market which the Commerce Clause intended to be open to non-local competitors. More specifically, New Jersey is regulating the market for solid waste processing and disposal services in each of the districts by directing district consumers of those services to utilize a favored service provider who, in the absence of exceptional circumstances, operates a local facility. It necessarily follows, we conclude, that any Commerce Clause analysis of New Jersey's flow control regulations must employ the heightened scrutiny test and that the district court erred by subjecting them only to the balancing test of Pike.

Atlantic Coast Demolition & Recycling, Inc. v. Board of Chosen Freeholders of Atlantic Cty., 48 F.3d 701, 710-11 (3d Cir. 1995) (emphasis added).

A state law requiring all transactions for a particular commodity to pass through a state program or single wholesaler or retailer, whose price would be set by government regulation, could be viewed as analogous to the Clarkstown ordinance requiring that all waste be processed through the local facility. Both regimes establish a barrier to the local market for out-of-state businesses, direct all business through a local entity, and regulate the price for business passing through the exclusive entity.

Even though a state regulatory regime calling for exclusivity could be drafted to be textually non-discriminatory, it would still involve regulation favoring an in-state program, retailer or wholesaler, just as Clarkstown favored a single local waste processing facility. As a result, a court may similarly deem a state law establishing an exclusive means by which commodities may be sold in the state as "more acutely" protectionist than other laws that have been found to discriminate against interstate commerce and were invalidated by the Court.

It is true that the Clarkstown law appeared to keep processing prices above market, whereas the intent of a Vermont effort to establish an exclusive wholesaler would be to bring prices down. This difference would not insulate a Vermont statute from attack, because the Carbone opinion focused primarily on the exclusive effect of the ordinance, not on the goal of above-market prices.

3. Public Utility Context

The existence of public utility exclusive franchises suggests that at least under certain circumstances states are free to establish exclusive entities through which commodities must be channeled before they are sold at retail.

The longstanding existence of exclusive utility franchises does not provide a clear path for an exclusive statute in Vermont. At least two features may distinguish utilities from other commodities that are typically freely sold in interstate commerce. These factors include:

a. The monopoly status of utilities has long historical acceptance and recognition by all states and Congress.

b. The natural monopoly feature of utility service means that competition, under certain facts, can produce uneconomical and socially undesirable duplication of transmission and distribution systems, as well as safety and reliability concerns growing out of uncontrolled development of the infrastructure.

This section first reviews some of the Supreme Court decisions applying Commerce Clause analysis to state laws affecting public utilities. It then describes a recent Supreme Court decision that may provide some insight into how the Court may distinguish the public utility context from other state regulation restricting competitors.[1]

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[1] Some states also control the distribution of alcohol through legislation restricting competition. We have not researched this area because of its overlap with the 21 Amendment of the U.S. Constitution. The 21st Amendment, section two declares: "The transportation or importation into any State, Territory , or possession of the United States for delivery or use therein of intoxicating liquors, in violation of the laws thereof, is hereby prohibited."

The Supreme Court has held that the 21st amendment does not repeal the Commerce Clause with respect to state regulation of the importation or transportation of alcohol, but it changes the equation, giving states "wide latitude" to regulate the transportation and importation of alcohol. Joseph E. Seagram & Sons, Inc. v. Hostetter, 384 U.S. 35, 42 (1966). It is because of this difference in Commerce Clause analysis applicable to alcohol that we have limited our research in area. In short, the leeway states have to restrict commerce in alcohol does not insulate from attack similar restrictions when applied to the prescription industry.

a. Commerce Clause Analysis in the Public Utility Context

There is no general exemption from the Commerce Clause for state regulation of public utilities. In Arkansas Electric Cooperative Corp. v. Arkansas Public Service Commission, 461 U.S. 375, 391 (1983), the Court noted that "[o]ur constitutional review of state utility regulation in related contexts has not treated it as a special province insulated from our general Commerce Clause jurisprudence." Thus in New England Power Co. v. New Hampshire, 455 U.S. 331, 334-36 (1982), the Supreme Court invalidated an order of the New Hampshire Public Utility Commission that required the New England Power Company to reserve for New Hampshire residents a particular amount of low-cost power generated within the state. In Wyoming v. Oklahoma, 502 U.S. 437 (1992), the Supreme Court invalidated a state statute that required that all coal-fired electricity plants located within the state of Oklahoma burn at least ten percent Oklahoma-mined coal. The Court noted that the question of which level of scrutiny to apply to the protectionist measure was "not a close call." Id. at 800 n.12.

None of these cases addresses the constitutionality of the state's grant of an exclusive. Indeed, one federal court has stated that only one Supreme Court case has involved "a Commerce Clause challenge ... [to] the exclusionary effects of a monopoly created by a state public utility regulatory scheme." Atlantic Coast Demolition & Recycling, Inc. v. Board of Chosen Freeholders of Atlantic County, 48 F.3d 701 (3rd Cir. 1995).

That Supreme Court case was decided in 1951. Panhandle Eastern Pipe Line Co. v. Michigan Public Service Commission, 341 U.S. 329 (1951). In Panhandle Eastern, the Court upheld a state utility commission's refusal to allow an out-of-state natural gas supplier to sell natural gas to industrial consumers in an area where a Michigan public utility had been granted an exclusive certificate of public convenience and necessity. The decision was based largely on the distinction between wholesale and retail sales of natural gas, a distinction the Court had relied upon in earlier cases.

Since 1951, however, the Commerce Clause law has developed considerably and the Court no longer applies the retail/wholesale distinction in utility cases, see Arkansas Electric Cooperative, supra. These changes raise doubts as to whether the Supreme Court would address a challenge similar to Panhandle Eastern the same way today.

We were able to locate only one recent discussion of how the Commerce Clause may apply to a challenge to a state utility's exclusive franchise. In Atlantic Coast Demolition & Recycling, supra, the court addressed a waste flow control statute similar to the Clarkstown ordinance at issue in Carbone. New Jersey attempted to distinguish the ordinance in Carbone, arguing that Clarkstown's transfer station was not a regulated public utility, while New Jersey's designated waste facilities constituted regulated public utilities. Due to this distinction, New Jersey argued, the court should subject its program to the balancing test of Pike v. Bruce Church, rather than the strict scrutiny test applied in Carbone.

The court rejected this argument, concluding that rigorous scrutiny would be applied to a

Commerce Clause challenge to the exclusive service territories of public utilities:

> Now that the Supreme Court has rejected [the wholesale/retail] distinction and made it clear in Arkansas Electric that public utilities regulation is not a special category for Commerce Clause purposes, it well may be that the heightened scrutiny test would be applied to a situation like that presented in Panhandle Eastern where an out-of-state firm challenges its exclusion from the local franchise market. A strong argument can be made that the rationale in C & A Carbone would require use of this test. See 114 S. Ct. at 1682 (finding the ordinance discriminatory because "it allows only the favored operator to process waste that is within the limits of the town" and "no less discriminatory because in-state or in-town processors are also covered by the prohibition"). We do not suggest, however, that traditional public utilities regulation of retail sales would be invalidated by heightened scrutiny. Where the regulation is addressed to a utility, like a local gas utility and unlike Atlantic Coast, whose service requires a tangible distribution system, a franchise monopoly may be the only economically feasible alternative.

Id. at 714-15. The Court then went on to apply heightened scrutiny and invalidate the New Jersey waste regulations.

According to the court's discussion in Atlantic Coast, while a court may apply heightened Commerce Clause scrutiny to a public utility's exclusive franchise, there may be unique features that would sustain the burden on interstate commerce, namely that exclusivity "may be the only economically feasible alternative." In the context of waste processing, that court determined that exclusivity was not the only feasible alternative.

b. The Supreme Court's General Motors' Decision

In the recent case of General Motors Corp. v. Tracy, supra, the Supreme Court addressed a challenge to an Ohio tax which discriminated in favor of Ohio natural gas public utilities. The case may shed some light on how the Supreme Court would respond to a challenge to an exclusive utility franchise.

The Ohio law at issue in General Motors exempted from general sales and use taxes natural gas sales by state-regulated gas utilities. The taxes applied to sales of natural gas by other in-state and out-of-state sellers, who challenged the tax under the Commerce Clause. Ultimately, the Court treated the Commerce Clause challenge as a threshold question of whether the out-of-state sellers and the state-regulated gas utilities are "similarly situated for constitutional purposes." Id. at 299. The Court upheld the tax on the grounds that it was not discriminatory because the history of state regulation of the natural gas industry distinguished the franchisees from independent marketers to the point that the enterprises should not be considered similarly situated so as to make the tax facially discriminatory.

The Court's thorough review of the natural gas industry and its regulation, which underpinned its decision to uphold the law, may indicate how a court would view public utility franchises as distinguishable from a state's effort to establish a franchise for a commodity -- prescription drugs -- that otherwise has been freely bought and sold in interstate commerce. The Court reviewed the history and current conditions of the natural gas industry, discussing, inter alia, the industry's natural monopoly characteristics, the establishment of federal regulation and Congress's own recognition of state utility regulations, as well as the state's interest in protecting captive customers and in the health and safety of its citizens. It also noted the universal recognition of the need for regulated gas utilities, citing the relevant statutes from all 50 states.

The General Motors decision initially discussed how economic factors brought about the need for comprehensive state regulation:

> [T]he States' ... experiments with free market competition in the manufactured gas and electricity industries ... dramatically underscored the need for comprehensive regulation of the local gas market. Companies supplying manufactured gas proliferated in the latter half of the 19th century and, after initial efforts at regulation by statute at the state level proved unwieldy, the States generally left any regulation of the industry to local governments. ... Many of those municipalities honored the tenets of laissez-faire to the point of permitting multiple gas franchisees to serve a single area and relying on competition to protect the public interest. The results were both predictable and disastrous, including an initial period of "wasteful competition," followed by massive consolidation and the threat of monopolistic pricing. The public suffered through essentially the same evolution in the electric industry. Thus, by the time natural gas became a widely marketable commodity, the States had learned from chastening experience that public streets could not be continually torn up to lay competitors' pipes, that investments in parallel delivery systems for different fractions of a local market would limit the value to consumers of any price competition, and that competition would simply give over to monopoly in due course. It seemed virtually an economic necessity for States to provide a single, local franchise with a business opportunity free of competition from any source, within or without the State, so long as the creation of exclusive franchises under state law could be balanced by regulation and the imposition of obligations to the consuming public upon the franchised retailers.

> When federal regulation of the natural gas industry finally began in 1938, Congress, too, clearly recognized the value of such state-regulated monopoly arrangements for the sale and distribution of natural gas directly to local consumers.
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> For 40 years, the complementary federal regulation of the interstate market and congressionally approved state regulation of the intrastate gas trade thus endured unchanged in any way relevant to this case. The resulting market structure virtually precluded competition between LDC's and other potential suppliers of natural gas for direct sales to consumers, including large industrial consumers.
>
> To this day, all 50 States recognize the need to regulate utilities engaged in local distribution of natural gas. Ohio's treatment of its gas utilities has been a typical blend of limitation and affirmative obligation.

Id. at 289-95 (citations and footnotes omitted; emphasis added).

Ultimately, the Court concluded that the history and economics combined with the various obligations the states imposed on public utilities distinguished them from the out-of-state sellers for purposes of Commerce Clause analysis:

> The fact that the local utilities continue to provide a product consisting of gas bundled with the services and protections summarized above, a product thus different from the marketer's unbundled gas, raises a hurdle for GMC's claim that Ohio's differential tax treatment of natural gas utilities and independent marketers violates our "virtually per se rule of invalidity."

Id. at 297-98 (citations omitted).

The Supreme Court's decision General Motors suggests that a combination of special factors would be considered in a Commerce Clause challenge to a state public utility franchise. Many, if not most, of these features are distinguishable from commodities that otherwise have been freely exchanged in interstate commerce, including pharmaceuticals. Perhaps most significantly, there is no long-running federal recognition of the need for and benefits of state regulation of exclusive franchises.

4. Conclusion

Outside the utility context, state attempts to limit out-of-state businesses' access to local consumers have been invalidated by judicial application of the "rigorous" scrutiny standard of Commerce Clause review. In the public utility context, research has uncovered few cases challenging a state's right to close off access to local consumers by establishing exclusive retail franchises. When other aspects of public utility law have been challenged, the Supreme Court has applied normal Commerce Clause analysis, including the per se rule to invalidate discriminatory laws and the balancing test to non-discriminatory laws. Case law does indicate, however, that a challenge to a public utility's exclusive franchise could be distinguished from a similar challenge to an exclusive state regulatory regime for non-utility commodities. Public utilities are largely distinct creatures of law, economics, engineering and history, generally not comparable to other goods and services traded in interstate commerce.

D. The "State-as-Market-Participant" Exception to the Commerce Clause

States may favor local economic interests when they act as market participants. Reeves, Inc. v. Stake, 447 U.S. 429 (1980) (sustaining a restriction on the sale of state government-produced cement to state residents). This "market participant" exception to the negative Commerce Clause applies when the state acts as a market participant and not as a market regulator. As a market participant, the state-controlled wholesaler may favor in-state residents and businesses in making purchases and sales. Below we (a) explain variations of the market participant doctrine, (b) explore the distinction between market participant and market regulator and (c) address the relationship between states-as-market-participants and private contractors they hire.

1. Variations of the Market Participant Doctrine

The Supreme Court has recognized two variations of the market participant doctrine. The first variation is when the government itself enters the market as a producer, buyer, or seller. The most obvious example is when the state procures the various items necessary for administering government, e.g., computers and pencils. The Commerce Clause does not bar the state from making a policy decision to purchase those items from in-state sellers.

The Supreme Court, in Reeves, Inc. v. Stake, supra, applied similar reasoning to the converse situation of when the state becomes seller instead of buyer. In Reeves, South Dakota had entered the market as a cement processor because no private company was processing cement in the state. For years, an out-of-state buyer purchased cement from the state plant, but when the state decided that it would no longer sell cement for out-of-state users, the buyer brought suit, alleging the state's decision to refuse to sell out-of-state violated the Commerce Clause. The Court upheld the law, applying the market participant exception.

The Court distinguished Reeves in South Central Timber Development v. Wunnicke, supra. In South Central, an Alaska statute provided that all contracts for the sale of state-owned timber include provisions requiring that the timber be processed within the state. The Court declared the statute invalid because it imposed "downstream restrictions" on the market after the state had already sold the timber product.

Another variation on the market participant theme is when the state enters the market by using its general revenues to provide what the Supreme Court has called a "bounty." The leading example is Hughes v. Alexandria Scrap Corp., 426 U.S. 794 (1976). Alexandria Scrap concerned a Maryland program designed to remove abandoned automobiles from the state's roadways and junkyards. To encourage recycling of junk cars, a "bounty" was offered for every Maryland-titled junk car converted into scrap. Processors located both in and outside Maryland were eligible to collect these subsidies. However, the law imposed more exacting documentation requirements on out-of-state than in-state processors and made it less profitable for suppliers to transfer vehicles outside Maryland. The law caused a decline in the number of bounty-eligible hulks supplied to a Virginia plant (owned by the party challenging the Maryland program) from Maryland sources. 426 U.S. at 801.

When the law was challenged by out-of-state processors as unfairly favoring in-state processors, the Court responded:

> Maryland has not sought to prohibit the flow of hulks, or to regulate the conditions under which it may occur. Instead, it has entered into the market itself to bid up their price .... as a purchaser, in effect, of a potential article of interstate commerce [and has restricted] ... its trade to its own citizens or businesses within the State.

Id. at 806-08 (emphasis added).

Relatedly, the case law is clear in holding that state legislation may promote local economic interests if the costs of promotion are paid by in-state residents. For example, a state may give local industries direct subsidies or tax relief, although a state may not shift the cost of supporting local economic interests to out-of-state residents. In other words, while a state may subsidize local business, it may not create a nondiscriminatory tax against all producers, but then channel the proceeds directly back to in-state producers. For example, a state cannot tax all milk sold by producers to in-state retailers and then distribute the tax to in-state farmers. See West Lynn Creamery, Inc. v. Healy, 512 U.S. 186 (1994).

2. The Distinction Between Market Participant and Market Regulator

The market participant doctrine applies only to actions taken by a state entity acting in a similar capacity as a private business. As described by the Supreme Court, the market participant doctrine "differentiates between a State's acting in its distinctive governmental capacity, and a State's acting in the more general capacity of a market participant." New Energy Co. of Indiana v. Limbach, 486 U.S. 269, 277 (1988). In other words, a state-run business may act just as a private business in deciding to purchase only local goods or sell to local citizens.

Language in C & A Carbone, supra, supports this distinction between the creation of a market participant and the simultaneous enactment of regulation protecting the market participant through methods that discriminate against interstate commerce:

> Clarkstown maintains that special financing is necessary to ensure the long-term survival of the designated facility. If so, the town may subsidize the facility through general taxes or municipal bonds. But having elected to use the open market to earn revenues for its project, the town may not employ discriminatory regulation to give that project an advantage over rival businesses from out of State.

511 U.S. at 394 (citation omitted).

The ordinance challenged in Carbone repeatedly refers to the solid waste transfer facility as a "town operated" facility, see appendix to the Court's decision, and the Supreme Court simply refers to the entity operating the facility as a "private contractor." Also, Justice Souter's dissent in Carbone stated:

> Clarkstown's transfer station is essentially a municipal facility, built and operated under a contract with the municipality and soon to revert entirely to municipal ownership. This, of course, is no mere coincidence, since the facility performs a municipal function that tradition as well as state and federal law recognize as the domain of local government.

511 U.S. at 417 (Souter, J., dissenting). Despite the Court's recognition of the town's pervasive role in the waste transfer facility, there was no discussion in the case of whether the market participant doctrine applied. It would appear that the market participant doctrine was never raised in Carbone because target of the challenge was the ordinance's regulatory aspect, not its proprietary aspect.

On the other hand, in New Energy Co. of Indiana v. Limbach, supra, Ohio expressly offered the market participant doctrine as a defense to the charge of discrimination. Ohio's statute gave a sales tax credit to fuel dealers for each gallon of ethanol sold for motor vehicles. The credit was made unavailable to ethanol coming from a state which did not grant tax advantages to Ohio-produced ethanol and was limited, for ethanol coming from a state which did allow credit for Ohio-produced ethanol, to an amount equivalent to that which such state allowed. The Court rejected Ohio's market participant defense, concluding that the state action ultimately at issue -- the assessment and computation of taxes -- is a governmental activity and "cannot plausibly be analogized to the activity of a private purchaser." 486 U.S. at 278.

The state of New Jersey, in Atlantic Coast Demolition & Recycling, described supra, also attempted to defend its exclusive waste flow program with the market participant. The state argued that its waste disposal program incorporating Carbone-type flow control provisions entitled it to the market participant exception because under state law New Jersey either participates (or directs local government entities to participate) in the waste disposal market as sellers and purchasers of waste disposal services and disposal capacity. Individual districts, the state argued, "sell" waste disposal services through the designated disposal facilities, and where a district has opted not to own or operate the designated facilities directly, it "purchases" services for "resale" by contracting with private facilities for the provision of waste disposal services. Therefore, the state contended, "the waste flow regulations simply represent a means by which the state manages the districts' market participation and the regulations are therefore protected from Commerce Clause scrutiny under the market participant doctrine." Atlantic Coast 48 F.3d at 716-17.

The court agreed with the state's characterization of the districts' activities under the statute as involving purchases and sales of disposal service and capacity, i.e., that at least for some purposes, the state laws created market participants. However, that the districts operated as market participants did not immunize the regulatory aspects of flow control ordinances:

> When a public entity participates in a market, it may sell and buy what it chooses, to or from whom it chooses, on terms of its choice; its market participation does not, however, confer upon it the right to use its regulatory power to control the actions of others in that market.
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> ***
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> Under New Jersey's solid waste disposal program, the districts are doing more than making choices about what waste they will accept even in those instances where the district owns the designated facility. The waste flow regulations purport to control the market activities of private market participants. Those regulations do not concern only the manner of operation of the government-owned or government-managed designated disposal facilities; they require everyone involved in waste collection and transportation to bring all waste collected in the district to the designated facilities for processing and disposal. They do not merely determine the manner or conditions under which the government will provide a service, they require all participants in the market to purchase the government service--even when a better price can be obtained on the open market. New Jersey's waste flow control regulations were thus promulgated by it in its role as a market regulator, not in its capacity as a market participant. As a result, those regulations are not immune from review under the Commerce Clause.

Id. at 717.

3. States May Hire Private Contractors to Serve Their Market Participant

We have found no reason why a state would be prohibited from hiring a private entity to perform services for an entity that qualifies as a market participant. We have identified no cases in which the market participant exception was denied because a state contracted out its services instead of using state employees.

E. State Regulation Incorporating Reference Prices

A version of price regulation is the use of reference prices. These raise special issues under the Commerce Clause. We discuss three possibilities here: a requirement of "best price," a prohibition against discrimination, and regulations that tie state prices to a federal benchmark.

1. Requirement of "Best Price" or Nondiscrimination

A state might consider using benchmarks based on private transactions, within the state or outside the state. A state statute limiting in-state prices to those charged in out-of-state sales would be invalid. "No state may require sellers to charge the same price within its borders as they charge elsewhere." K-S Pharmacies v. American Home Corp., 962 F.2d 728, 730 (7th Cir. 1992) (citing Healy and Brown-Forman).

Consequently, a state may not require that a seller extend to all buyers within the state the best price offered by that seller in some other state:

> Such statutes, the Supreme Court has held, assert extraterritorial jurisdiction of a kind denied to states by the "negative" or "dormant" commerce clause. Any statute of the form "charge in this state the same price you charge outside it" carries the implied command: "Charge outside this state the same price you charge inside it." This latter, implied (but inseparable) command, the [Supreme] Court held, is a forbidden attempt to exercise extraterritorial power.

Id. (citations to Healy and Brown-Forman omitted).

On the other hand, a state may require that the seller extend to all buyers within the state the best price offered by that seller in the same state.[2]

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[2] In K-S Pharmacies, supra, the court upheld a Wisconsin statute, Wis. Stat. ' 100.31(2), prohibiting sellers of prescription drugs from discriminating against purchasers within the state. A group of pharmacies brought suit under the statute, contending that the manufacturer violated the law by selling at a lower price to competitors. The manufacturer argued for an interpretation

Finally, a state statute does not control commerce outside the state where (a) the statute prohibits price discrimination within the state and (b) federal law dictates that a supplier must sell to purchasers in another state at the same price. See Exxon Corp. v. Governor of Maryland, 437 U.S. 117 (1978) (dismissing Commerce Clause claim where extraterritorial effect arose from requirements of Robinson-Patman Act and not the Maryland statute prohibiting price discrimination).

2. Implications of Regulations that Tie State Prices to a Federal Benchmark

a. Introduction and Overview

As an alternative to basing the reference price on private transactions, a state might wish to base it on the Federal Supply Schedule (FSS). This type of reference raises questions similar to those discussed in the context of private reference prices. Because of the complex and unique features of the FSS, we explore it here in detail.

A court may strike a state price regulation statute because it (a) forces sellers to take the state-regulated price into account in setting prices in transactions outside the state for other purchasers, or (b) deprives non-state purchasers of competitive advantages that they otherwise would use to obtain lower prices. Courts will always focus on the statute's "practical effect."

This section analyzes how these Commerce Clause principles might apply to state legislation establishing a prescription pricing or rebate program that effectively limits state prices to the price that the U.S. government pays for pharmaceuticals under the Federal Supply Schedule (FSS). It concludes that manufacturers could make a plausible challenge to the FSS pricing scheme on the basis that it controls commerce that takes place wholly outside the state. Specifically, challengers could argue that a state-level FSS reference is likely to cause manufacturers to increase the FSS price to the federal government.

In order to help avoid the Commerce Clause problems associated with the FSS benchmark, an alternative benchmark, such as the average manufacturer price might be possible. Such a benchmark would allow a manufacturer to set prices for customers in other states without automatically setting the price for the entire Vermont market.

This section first explains why tying prices (or rebates) to the FSS schedule will have a

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of the statute declaring that sellers in Wisconsin must extend to all purchasers their lower sale price anywhere, even outside the state, and thus that the statute violated the Commerce Clause. After observing that the manufacturer's argument would render the statute invalid under the Commerce Clause, the court interpreted the statute to apply only to the lowest price offered to purchasers within Wisconsin, and upheld its validity.

practical effect on out-of-state commerce. It then explains that a court either may (1) find that the FSS benchmark regulation is invalid per se or (2) if it does not find that the regulation is invalid per se, analyze the regulation's benefits and burdens to determine its validity under the Commerce Clause. The section then turns to a discussion of the implications of using a potential alternative to the FSS. The section concludes by discussing whether a reference price based on the average manufacturer price would improve the statute's chance of validity.

b. Tying Prices (or Rebates) to the Federal Supply Schedule Will Have a Practical Effect on Out-of-State Commerce

i. Overview of the FSS

The Federal Supply Schedule (FSS) for pharmaceuticals is a catalog of drug prices from which the federal government spends more than $1 billion annually. The bulk of the purchases are made by the Veteran's Administration, which has been delegated administration of the FSS by the General Services Administration.

The process of establishing the FSS for pharmaceutical drugs is a complex one. The following aspects of the pricing process are relevant to the Commerce Clause analysis:

- Term. As we understand it, manufacturers enter into agreements with the federal government setting the prices for pharmaceuticals for a one-year period.

- Price. The price charged to certain protected agencies must be less than 76% of the non-federal average price (this is known as the "Federal Ceiling Price" or "FCP"). 38 U.S.C. ' 8126. The federal government may negotiate a lower price. The government often avoids protracted price negotiations by basing the FSS on prices that the manufacturer charges to its "most-favored customer." As a result of these negotiations, prices for those drugs covered by the Veterans Health Care Act are "on average, about 28 percent below the FCP." U.S. General Accounting Office, "Effects of Opening the Pharmaceutical Schedule are Uncertain" at 6 (July 10, 1997) (hereinafter cited as "GAO Testimony") (commenting on federal proposal to open FSS pricing to state governments).

- Manufacturer Considerations. In negotiating the FSS, manufacturers take into account that the federal government's FSS schedule is a limited program. Among the factors that manufacturers cite include the benefits that will result from the use of their products by physicians training at VA hospitals. GAO Testimony, p. 3.

ii. Possible Effects of the State Law on the Manufacturers' Negotiations With the Federal Government

A state's adoption of the FSS benchmark may have the effect of impeding the federal government's ability to use its competitive advantages to obtain low prices for pharmaceuticals. In negotiating the FSS price with the federal government, the manufacturer's calculations would change. To determine the effect on its profits of agreeing to a particular price, the manufacturer would have to take into account not only federal purchasers of the product, but all those segments of the market for which the benchmark is applicable. This consideration would likely drive the FSS price higher. As the GAO has explained: "The larger the market, the greater the economic incentive would be for a manufacturer to raise schedule prices to limit the impact of giving low prices to more purchasers." GAO Testimony, p. 2.

Moreover, if more than one state adopted the FSS as a benchmark, there would be even greater upward pressure on the FSS:

> Manufacturers are likely to respond to the broader use of the FSS by excluding some federal purchasers from FSS prices (where allowable) and raising FSS prices. The GAO reported the VA's assumptions that as a result of opening the FSS to state purchasers, "(1) drug manufacturers would eliminate FSS pricing for all drugs not covered by the Veteran's Health Care Act, forcing federal purchasers to buy these generic drugs at higher wholesale prices, and (2) FSS prices for all drugs covered by the act would rise to the FCPs."

GAO Testimony, p. 7.

iv. Possible Effects on Customers in Other States

Just as a state's tying pharmaceutical prices (or rebates) to the FSS may affect federal transactions, it may affect prices to customers in other states. If state regulations tying prices to the FSS cause manufacturers to increase the FSS, that increase could occur in various ways.

For example, manufacturers' FSS agreements with the federal government often tie the FSS price to the price the manufacturer sells to its "most-favored customer." Manufacturers might therefore raise prices to favored private customers in order to boost the FSS prices that are based on most-favored customer prices. Manufacturers might abandon most-favored customer prices altogether and negotiate higher FSS prices with the federal government.[3] By depriving

[3] We have considered the possibility that federal government transactions that are subject to federal law do not constitute interstate commerce for purposes of Commerce Clause analysis. We have not found cases in which the courts have evaluated the impact of a state statute on federal government transactions under the Commerce Clause. Nor have we found cases which state that federal government contracts are not interstate commerce for purposes of the Commerce Clause.

out-of-customers of competitive advantages they would otherwise enjoy relative to Vermont customers, a state's use of the FSS could raise Commerce Clause problems, as discussed in more detail below.

v. Potential for Conflict with Other States

A state's use of an FSS Benchmark is unlikely to result in conflict with other state statutes. The Healy case, discussed in Part One: I.B.1.b, supra, dictates that "the practical effect of ... a statute must be evaluated . .. by considering how the challenged statute may interact with the legitimate regulatory regimes of other states and what effect would arise if not one, but many or every, state adopted similar legislation." 491 U.S. at 336.

The Healy Court found that existing and potential states' affirmation and beer pricing statutes would "create just the kind of competing and interlocking local economic regulation that the Commerce Clause was meant to preclude." 491 U.S. at 337. This effect would occur because each state would impose a cap on the others based upon the prices charged in the preceding month, resulting in a "price gridlock" and a "short-circuiting of normal pricing decisions based on local conditions" on a scale reserved by the Commerce Clause to the Federal Government. Healy, 491 U.S. at 340.

A state law tying pharmaceutical prices to a benchmark established by the federal government, as opposed to one based on pricing decisions in other states, probably reduces the risk of conflicting statutes. If all states adopted the same FSS benchmark, compliance would not be a problem for manufacturers. Nor would the statutes "interlock" because they would not make reference to other states' statutes. However, as described in the preceding section, the impact on prices to other customers would be greater the more states followed Vermont's lead. It is possible that specific terms of various state statutes adopting the FSS might lead to conflicts, but there is no basis for predicting such an outcome at this time.

c. The FSS Benchmark Has Certain Characteristics of a Per Se Invalid Regulation

i. Case Law Background

Setting a schedule of prices for sales outside of the state could be viewed as constituting an exercise of control over out-of-state transactions, in violation of the rules announced by the Supreme Court in Healy and Brown-Forman. See discussion in Part One: I.B.1.b. Brown-Forman held invalid a law requiring liquor producers to affirm that they would not sell to any customer out of New York at a lower price than the price it charged New York wholesalers. Once the affirmation was made, the producers could not lower out-of-state prices without violating New York law.

In Healy, the Court invalidated a Connecticut beer price affirmation statute that required beer producers to post prices for the month and guarantee that the prices were no higher than prices charged in bordering states at the time of posting. This statute differed from the Brown-Forman statute, which applied prospectively, in that sellers could change out-of-state prices without Connecticut's approval. The Court found that this "contemporaneous" affirmation statute still had the practical effect of controlling commercial activity outside of Connecticut because a producer would have to take the Connecticut statute into account in negotiating prices with out-of-state customers:

> On January 1, when a brewer posts his February prices for Massachusetts, that brewer must take account of the price he hopes to charge in Connecticut during the month of March. Not only will the January posting in Massachusetts establish a ceiling price for the brewer's March prices in Connecticut, but also, under the requirements of the Massachusetts law, the brewer will be locked into his Massachusetts price for the entire month of February....

Healy, 491 U.S. at 338. Similarly, because New York required promotional discounts to remain in effect for 180 days and the Connecticut regulation considered promotional discounts as price reductions, the manufacturer offering promotional discounts in New York would have to lock in Connecticut prices for 180 days at the discounted price. The statute also discouraged volume discounts in other states.

A state law that restricts the ability of a seller to set out-of-state prices based upon local competitive factors, by requiring the seller to consider the effect on prices in the regulating state, may constitute forbidden control of prices in other states. The Court in Healy observed that the Connecticut law would deprive producers and out-of-state customers of competitive advantages that would result in lower prices:

> [A]s the Court of Appeals concluded, '[a] brewer can . . . undertake competitive pricing based on the market realities of either Massachusetts or Connecticut, but not both, because the Connecticut statute ties pricing to the regulatory schemes of the border states. In other words, the Connecticut statute has the extraterritorial effect, condemned in Brown-Forman, of preventing brewers from undertaking competitive pricing in Massachusetts based on prevailing market conditions.

491 U.S. at 338, citing 849 F. 2d at 759.

The Brown-Forman Court expressed similar concerns about statutes that require out-of-state entities to surrender "whatever competitive advantages they may possess." Brown-Forman, 476 U.S. at 580. As one commentator has observed:

> The Court in Brown-Forman invoked this principle, finding the New York affirmation statute abhorrent in part because it was

> designed to convey competitive advantages upon consumers in one state that those consumers would not have had in the absence of the affirmation statute. Such an effect is improper when those advantages are acquired to the detriment of consumers in other states where the markets might favor lower prices.

Greenberg, Ward A., "Liquor Price Affirmation Statutes and the Dormant Commerce Clause," 86 MICH. L. REV. 186, 203 (1987).

ii. Application

The concerns of the Court in the Brown-Forman and Healy opinions may apply to a state's tying of pharmaceutical prices to a federal benchmark. As explained above, the FSS benchmark law could affect competitive advantages enjoyed by the federal government and most-favored customers in other states. In negotiating the FSS (or the price to a "most-favored customer" that determines the FSS), manufacturers would have to be prepared to offer the same price to customers in the states adopting the FSS benchmark. Moreover, assuming that the FSS agreement is in effect for a period of a year or more, the manufacturer negotiating the FSS prices would have to consider the prices it planned to charge in all such regulating states for a corresponding period.

d. Even if Not a Per Se Violation, a Benchmark Program Would Be Analyzed Based upon Its Benefits and Burdens

Assuming that a court would not view a state law's reference to FSS prices as per se discriminatory, the law could still be challenged as being excessively burdensome on interstate commerce relative to its benefits.

It is difficult to predict how a court would balance benefits and burdens, and no cases specifically address this issue. The court would assess the economic effects of the state's incorporation of FSS prices, and ask whether the state had equally effective alternatives. Finally, if the Court accepts that the statute would likely result in increased FSS prices, it may conclude that the statute would be ineffective in achieving the state's drug price reduction goal.

e. Potential Alternative: Average Wholesale Price

Using an objective benchmark that is not tied to a manufacturer's competitive pricing decisions could avoid particular Commerce Clause problems. If the state adopts the average wholesale price, the statute will not affect directly the competitive position of buyers and sellers in other markets. Manufacturers would be able to set prices elsewhere without at the same time setting prices for the entire state of Vermont. Such a provision would be an attempt to obtain the benefits of national competition for Vermont citizens, but the effect on manufacturer sales elsewhere would be far less direct.

The use of the average wholesale price benchmark requires further analysis. While we think that this may be a more viable option than the FSS benchmark, there may be other legal and practical concerns raised by such an approach. Some of these are addressed in Part One: II.C.4.a, which discusses possible preemption problems with such an approach.

F. Price Disclosure

If price disclosure obligations are enacted as part of a voluntary program, for example, a program which qualified under the market participant doctrine, the Commerce Clause should not pose any problems. Manufacturers and wholesalers would participate in the program on a voluntary basis, and they would be able to take into account the disclosure requirements in their decision to participate in the state program.

The question of mandatory price disclosure requirements outside of a statewide program may raise Commerce Clause issues, however. As Part One: I.B.1 explains, a state may not regulate an out-of-state company's transactions occurring in another state. The constitutional principles that would preclude a state from regulating or taxing transactions occurring in another state would likely preclude the state from requiring an out-of-state company to disclose information about transactions occurring in another state. Price disclosure requirements in federal and other state programs, for example, are required only for those participating in the relevant federal or state program. In other words, the analysis that precludes price regulation of out-of state transactions may apply to a price disclosure requirement, thus precluding a state from requiring an out-of-state company to provide price information from transactions occurring out the state.

A different analysis would apply if the disclosure requirement is placed only on in-state transactions. Since such disclosure requirements would apply only to transactions occurring within the state, they should not pose a significant barrier to manufacturers and wholesalers wishing to import into the state. Again, as with in-state price regulation, such legislation would likely be subject to the Commerce Clause balancing test. <u>See</u> Part One: I.B.2.

II. SUPREMACY CLAUSE

A. Introduction

The U.S. Constitution provides that federal laws shall be "the supreme law of the land." Article VI, cl. 2. This provision, known as the "Supremacy Clause," means that federal law can nullify a state law. In other words, state laws can be "preempted" by federal laws. Because there is a large body of federal law that may relate to the legislative options the Committee is considering -- for example, pharmaceutical products and labeling, market regulation, health care, and pharmaceutical procurement -- it is important to be aware of potential preemption issues.

After an overview of the preemption doctrine, the potential preemptive effects of specific areas of federal law are considered. As seen below, with certain limitations, Congress has appeared to leave some room for state action. A number of the laws examined are noted in only abbreviated form because they are unlikely to raise any preemption issues.[4] The statutes are divided into two sections according to the potential risk of preemption.

When the Committee is closer to drafting of an actual bill, potential bill language should be analyzed in order to assess the potential for preemption under the statutes cited here, and perhaps under additional federal law, should it be implicated.

B. Overview of Supremacy Clause

Whether a federal law preempts state law depends on congressional intent. Congress may signal its intent to preempt by passing laws directly, or by delegating its preemption authority to a federal agency. Courts hesitate to find preemption, except where "the nature of the regulated subject matter permits no other conclusion, or [where] Congress has unmistakably so ordained." N.Y. State Dep't of Social Services v. Dublino, 413 U.S. 405, 413 (1973). The party asserting preemption carries the burden of proving congressional intent to preempt. The Supreme Court has summarized preemption doctrine as follows:

> It is well established that within constitutional limits Congress may pre-empt state authority by so stating in express terms. Absent explicit pre-emptive language, Congress' intent to supersede state law altogether may be found from a scheme of federal regulation so pervasive as to make reasonable the inference that Congress left no room for the States to supplement it, because the Act of Congress may touch a field in which the federal interest is so dominant that the federal system will be assumed to preclude enforcement of state laws on the same subject, or because the object sought to be obtained by the federal law and the character of obligations imposed by it may reveal the same purpose. Even where Congress has not entirely displaced state regulation in a specific area, state law is pre-empted to the extent that it actually conflicts with federal law. Such a conflict arises when compliance with both federal and state regulations is a physical impossibility

[4] In addition, the following statutes were briefly reviewed and determined to be unlikely to present a preemption problem for the legislative proposals under consideration: the Controlled Substances Act, Pub. Law 91-513; 84 Stat. 1242 (1970); 21 U.S.C. ' 801 et. seq.; the Controlled Substances Import and Export Act, Pub. Law 91-513; 84 Stat. 1285 (1970); 21 U.S.C. ' 951 et. seq.; the FDA Modernization Act of 1997, Pub. Law 105-111; 111 Stat. 2295 (1997); the Orphan Drug Act, Pub. Law 97-414, 96 Stat. 2049; and the Public Health Service Act, 42 U.S.C. ' 201 et seq.

> or where state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.

Pacific Gas & Electric v. State Energy Resources Conservation & Dev. Comm'n, 461 U.S. 190, 203-04 (1983)(internal quotations and citations omitted).

To summarize the Court's preemption analysis in Pacific Gas & Electric, congressional intent to preempt may be (a) clearly expressed in a federal statute or (b) implied. Courts have found implied Congressional intent to preempt state law in three general categories of situations: (1) where there is a need for uniform national standards; (2) where Congress has legislated in an area comprehensively, occupying the entire field of regulation, and leaving no room for state supplementation; or (3) where the state law actually conflicts with federal law and compliance with both state and federal law is physically impossible.

Illustrations of the each of the type of preemption include the following:

- Uniform national standards not required: California set standards measuring the maturity of avocados. The standards were higher than federal standards and served to bar some Florida avocados from California markets. Congress did not intend uniform standards; and compliance with minimum federal standards did not conflict with California's standards since Florida growers could comply with both standards. Florida Lime & Avocado Growers, Inc. v. Paul, 373 U.S. 132 (1963).

- Federal scheme does not "occupy the field": California moratorium on the construction of new nuclear plants, until a high-level nuclear waste disposal facility is approved by the federal government, was not preempted by the Atomic Energy Act. The state law was passed for purposes of economics, while the federal law was geared to safety. Pacific Gas & Electric, supra.

- Conflicting laws: State law established food labeling requirements, but did not allow for "reasonable weight variations." Federal law, designed to allow for value comparisons, allowed for reasonable variations to account for moisture loss during shipping. Jones v. Rath Packing Co., 430 U.S. 519 (1977).

- Conflict between state and federal -- partial preemption: Federal law providing that "no statement relating to smoking and health shall be required in the advertising of any cigarettes" other than the federally mandated warnings did not preclude state product liability claims, but did preclude state from mandating particular warnings. Later amendment to the federal law prohibiting states from enacting requirements "with respect to the advertising or promotion of any cigarettes the packages of which are labeled [in compliance with federal law]" preempted certain state law remedies relying on failure to warn in excess of federally mandated warnings. Cipollone v. Liggett Group, Inc., 505 U.S. 504 (1992).

- Conflict between state and federal law -- no preemption: A federally licensed nuclear facility, appealing the award of $10 million in punitive damages related to a worker's exposure to plutonium, argued that federal nuclear safety regulations preempted the state law claim. Despite its Pacific Gas & Electric decision (see above), the Supreme Court held that the nuclear facility had not met its burden of showing that Congress intended to preclude state-law remedies, including punitive damage awards. Punitive awards are not inconsistent with Nuclear Regulatory Commission civil penalties and do not "frustrate any purpose of the federal remedial scheme." Silkwood v. Kerr-McGee Corp., 464 U.S. 238, 257 (1984).

C. Federal Areas of Law Potentially Raising Preemption Issues

1. ERISA Preemption

a. Introduction

Some of legislative options relating to prescription drugs considered could implicate insurance and prescription benefit programs administered by employers. As a result, there is a risk that the legislation, or certain provisions of it, could be preempted by the federal Employee Retirement Income Security Act of 1974 (ERISA).

ERISA's express preemption language states:

> Except as provided in subsection (b) of this section, the provisions of this subchapter and subchapter III of this chapter shall supersede any and all State laws insofar as they may now or hereafter relate to any employee benefit plan ....

29 U.S.C. ' 1144(a)(emphasis added). An employee benefit plan is defined as any plan maintained:

> (1) by any employer engaged in commerce or in any industry or activity affecting commerce; or
>
> (2) by any employee organization or organizations representing employees engaged in commerce or in any industry or activity affecting commerce; or

(3) by both.

' 1003(a).

ERISA includes a "savings clause," which declares that states may regulate insurance by providing that "nothing in this subchapter shall be construed to exempt or relieve any person from any law of any State which regulates insurance . . . ." 29 U.S.C. ' 1144(b)(2)(A).

The statute also includes a "deemer clause" which prohibits the treatment of employee benefit plans as being the business of providing insurance. It states that

> an employee benefit plan .. [shall not] be deemed to be an insurance company or to be engaged in the business of insurance ... for purposes of any law of any State purporting to regulate insurance companies.

29 U.S.C. ' 1144(b)(2)(B).

In enacting ERISA, Congress intended to facilitate the administration of employee benefit plans by creating a uniform body of employee pension and benefit laws, thereby ensuring that plan administrators need only comply with only one set of regulations and not with conflicting state and local regulations. Among other provisions, ERISA imposes reporting and disclosure obligations, schedules for the vesting and funding of pension plans, standards of care and loyalty for plan administrators, and various other specific obligations for benefits plans and their administrators.

At the most general level, preemption of state law under ERISA occurs when a state law will influence the course of action taken by administrators of employee benefit plans. The scope of ERISA preemption is perhaps the broadest of any federal statute. The Supreme Court has called ERISA preemption "clearly expansive," New York State Conference of Blue Cross & Blue Shield Plans v. Travelers Ins. Co., 514 U.S. 645, 653-54 (1995), and has frequently noted its "broad scope." Metropolitan Life Ins. Co. v. Massachusetts, 471 U.S. 724, 739 (1985). However, the courts have generally struggled in defining the exact scope of preemption given the ambiguity in the statutory language.

Finally, it should also be kept in mind that ERISA may preempt a state law if the state law actually conflicts with one of the complex requirements of the statute.

b. Preemption Overview

Most court decisions on state health-care regulation and ERISA preemption involve three determinations: (1) whether the statute "relates" to ERISA-covered employee benefit plans, thereby falling under ERISA's express preemption provision; (2) if it does relate to a plan, whether the statute is exempt from ERISA preemption under ERISA's savings clause which allows states to regulate insurance companies; and (3) if the statute purports to regulate insurance, whether it impermissibly deems an employee health benefit plan as the business of insurance, thereby rendering the savings clause inapplicable.

The "relates to" language has been described in various decisions as involving two components: does the statute have (1) a reference to an employee benefit plan covered by ERISA, or (2) a connection with such a plan. See, e.g., District of Columbia v. Greater Washington Bd. of Trade, 506 U.S. 125, 129 (1992); Shaw v. Delta Air Lines, Inc., 463 U.S. 85, 96-97 (1983). The "reference to" test asks whether the statute contains a literal or implicit reference to ERISA covered plan. The "connection with" test requires examination of "the objectives of the ERISA statute as a guide to what state laws Congress intended to preempt." Prudential Ins. Co. of America v. National Park Med. Ctr., Inc., 154 F.3d 812 (8th Cir. 1998).

In a close case, some of the factors a court may consider in determining the preemptive effects of ERISA including the following:

- the extent to which the state law involves a state's traditional exercise of power (containment of health care costs has been recognized as such an exercise);
- whether the law risks subjecting plan administrators to conflicting state regulations;
- whether state law negates a provision of an ERISA covered plan;
- the law's impact on plan administration;
- the economic impact of the statute on ERISA plans (though some impact on the cost of employee benefit plans has been permitted, at least by some courts); and
- whether the state law is consistent with other provisions of ERISA.

c. The Supreme Court's Travelers Insurance Decision

The Supreme Court's leading case on ERISA preemption in the context of state efforts to contain health care costs is New York State Conference of Blue Cross & Blue Shield Plans v. Travelers Ins. Co., 514 U.S. 645 (1995). Travelers Insurance involved a New York statute regulating hospital rates for in-patient care. The statute established a standard rate for hospital patient treatment based on the average cost of treating the patient's medical problem rather than the cost of individual treatment. The law imposed surcharges on patients covered by commercial insurers and HMOs, but not from patients insured by Blue Cross/Blue Shield (Blues). The state justified the charge differentials on the ground that the Blues pay the hospitals promptly and efficiently, and -- "more importantly," the court noted -- the Blues provide coverage for many subscribers whom the commercial insurers would reject as unacceptable risks.

The private insurers argued, and the lower courts found, that ERISA preempted the law because the intended effect of the statute was to make the Blues more attractive relative to commercial insurers, which would affect what insurance plans ERISA administrators selected; thus, the law had "a connection with" and therefore "related to" an employee benefit plan and was preempted.

In an unanimous decision, the Supreme Court reversed, holding that the New York law was not preempted. The statute did not relate to an ERISA plan because

> [t]he surcharges are imposed upon patients and HMO's, regardless of whether the commercial coverage or membership, respectively, is ultimately secured by an ERISA plan, private purchase, or otherwise, with the consequence that the surcharge statutes cannot be said to make "reference to" ERISA plans in any manner.

Id. at 656.

Additionally, the Court observed:

> An indirect economic influence, however, does not bind plan administrators to any particular choice and thus function as a regulation of an ERISA plan itself; commercial insurers and HMO's may still offer more attractive packages than the Blues. Nor does the indirect influence of the surcharges preclude uniform administrative practice or the provision of a uniform interstate benefit package if a plan wishes to provide one. It simply bears on the costs of benefits and the relative costs of competing insurance to provide them. It is an influence that can affect a plan's shopping decisions, but it does not affect the fact that any plan will shop for the best deal it can get, surcharges or no surcharges.

Id. at 659-60. See also Boyle v. Anderson, 68 F.3d 1093 (8th Cir. 1995)(upholding Minnesota's health care reform legislation against preemption challenge alleging that preemption resulted from statute's passthrough to ERISA plans of a two percent gross receipts tax on health care providers and from reporting and spending cap requirements).

d. Examples of ERISA Preemption Cases

A Pennsylvania law prohibited "plans from . . . requiring reimbursement [from the beneficiary] in the event of recovery from a third party" was held to "relate to" employee benefit plans within the meaning of ' 514(a). The law was preempted because it "prohibited plans from being structured in a manner requiring reimbursement in the event of recovery from a third party" and "required plan providers to calculate benefit levels in Pennsylvania based on expected liability conditions that differ from those in States that have not enacted similar antisubrogation legislation," thereby "frustrating plan administrators' continuing obligation to calculate uniform benefit levels nationwide." FMC Corp. v. Holliday, 498 U.S. 52, 60 (1990).

In Mackey v. Lanier Collection Agency & Service, Inc., 486 U.S. 825 (1988), the Supreme Court said that ERISA preempts any state laws that relates to an employee benefit plan, even if the state law is consistent with ERISA's substantive requirements of ERISA. The Court held preempted a garnishment law that specifically exempted ERISA plans from an otherwise generally applicable garnishment provision.

The District of Columbia's Workers' Compensation Act provided for continuing health care benefits for employees eligible for workers' compensation benefits. It required that

> Any employer who provides health insurance coverage for an employee shall provide health insurance coverage equivalent to the exiting health insurance coverage of the employee while the employee receives or is eligible to receive workers' compensation benefits under this chapter.

In holding the statute was preempted, the Supreme Court's analysis was largely confined to a finding that the statute referred to an ERISA plan, resulting in preemption. District of Columbia v. Greater Washington Bd. of Trade, 506 U.S. 125 (1992).

e. State Laws Regulating Pharmaceuticals

i. "Any Willing Provider" Statutes

ERISA has been held to preempt state laws, known as "any willing provider" statutes, that are designed to permit patients to select their own health care providers under certain terms. Texas enacted such legislation relating to pharmaceuticals. The Texas statute required that health insurers and managed care plans allowing willing pharmacies to participate in their prescription network plans.

The statute provided in part that:

> ' 2. (a) A health insurance policy or managed care plan ... may not: (1) prohibit or limit a person who is a beneficiary of the policy from selecting a pharmacy or pharmacist of the person's choice to be a provider under the policy to furnish pharmaceutical services offered or provided by that policy or interfere with that person's selection of a pharmacy or pharmacist; (2) deny a pharmacy or pharmacist the right to participate as a contract provider under the policy or plan if the pharmacy or pharmacist agrees to provide pharmaceutical services that meet all terms and requirements and

> to include the same administrative, financial, and professional conditions that apply to pharmacies and pharmacists who have been designated as providers under the policy or plan; (3) require a beneficiary of a policy or participant in a plan to obtain or request a specific quantity or dosage supply of pharmaceutical products.

Texas. Ins. Code Ann. art. 21.52B, ' 2 (1997).

When a group of pharmacies sought to enforce the statute against Prudential Insurance Co., Prudential argued the statute was preempted by ERISA. Prudential offered group health insurance policies to employers and contracts to provide administrative services only to self-funded employer health plans, which are covered by ERISA. Prudential maintained health care networks, including pharmacy networks, for the participants and beneficiaries of both types of plans. Prudential would contract with pharmacies and allow participants to fill their prescriptions at predetermined dispensing fees and drug prices, in order to provide for quality control and lower prices.

As described by the U.S. Court of Appeals for the Fifth Circuit:

> The effect of the statute is that any pharmacist willing to abide by the terms of a Prudential network contract must be admitted to the network. The statute declares void any provision of a health insurance policy or managed care plan that conflicts with it. The statute does however exempt from the any-willing-provider requirement "a self-insured employee benefit plan that is subject to [ERISA]."

Texas Pharm. Ass'n v. Prudential Ins. Co. of America, 1997 U.S. App. LEXIS 12986 (5th Cir. 1997) (footnote omitted). The court had no problem in finding that the statute was preempted under ERISA, declaring that such "[g]arden variety employer health insurance plans, which are regulated under the Texas statute, are 'employee benefit plans' under ERISA, defined to include 'any plan ... established or maintained by an employer ... for the purpose of providing ... through the purchase of insurance or otherwise ... medical, surgical, or hospital care or benefits, or benefits in the event of sickness....'" Prudential, at *7 quoting from 29 U.S.C. ' 1002(1)(A)).

The Fifth Circuit in Prudential also examined the pharmacies' contention that the Texas statute was preserved by ERISA's savings clause (quoted above), which exempts state laws regulating insurance from ERISA's preemptive effects. Applying a Supreme Court test, the court held that the statute did not fit within the savings clause because the effect of the statute was not limited to insurance companies:

> [T]he Texas statute ... does not fall within the savings clause because it is not limited to entities within the insurance industry. Instead, it also applies to health maintenance organizations

> (HMOs), preferred provider organizations (PPOs), and other organizations tha tprovide health care services. Indeed, since the statute defines managed care providers to include HMOs, PPOs, or "another organization" that provides health care benefits, it applies to ERISA benefit plans themselves.

Prudential, at *11-12. The court gave the following examples as to how the statute would effect employee benefit plans without regulating insurance:

- even though the statute would not apply directly to a self-insured employer, if that employer signed up with an HMO or PPO, those organizations would be subject to the statute (even though no insurance company would be involved);

- a group of pharmacies wanting to offer a plan to an employer would be deemed an "other organization" under the statute and subject to its any willing provider requirements; and

- an employer offering health coverage through an insurance plan that did not cover prescriptions, but contracted separately with pharmacy to provide employees with prescription services, would fall within the statute.

Finally, the court refused to sever the portions of the statute regulated plans covered by ERISA from the permissible provisions, noting that the statute must "be limited to entities within the insurance industry."

In Prudential Ins. Co. of America v. National Park Med. Ctr., Inc., 154 F.3d 812 (8th Cir. 1998), a federal appeals court addressed an "any willing provider" statute designed to ensure "that patients . . . be given the opportunity to see the health care provider of their choice." Ark. Code Ann. ' 23-99-202. Prudential Ins. Co. of America v. National Park Med. Ctr., Inc., 154 F.3d 812 (8th Cir. 1998). The law forbid a health care insurer from

> [i]mposing upon a beneficiary of health care services under a health benefit plan any co-payment, fee, or condition that is not equally imposed upon all beneficiaries in the same benefit category, class, or co-payment level under the health benefit plan when the beneficiary is receiving services from a participating health care provider pursuant to that health benefit plan.

The court concluded that the statute's express and implicit references to ERISA subjected it to preemption:

> [T]he Arkansas PPA [patient protection act] expressly states that

> its provisions "shall not apply to self-funded or other health benefit plans that are exempt from state regulation by virtue of the federal Employee Retirement Income Security Act of 1974, as amended." Ark. Code Ann. ' 23-99-209. .... [T]his reference to ERISA is sufficient to preempt the Arkansas PPA.

154 F.3d at 823 (emphasis added). The court noted that implicit references to an ERISA plan are enough to cause preemption. For example, the statute declared, "it is a violation of this subchapter for any health care insurer or other person or entity to provide any health benefit plan providing for health care services that does not conform to this chapter" and that the PPA was intended "to provide the opportunity of providers to participate in health benefit plans." These implicit references, the court said, give rise to preemption.

The court distinguished Washington Physicians Serv. Ass'n v. Gregoire, 147 F.3d 1039 (9th Cir. 1998), which upheld a similar statute, on the grounds that the Washington statute at issue in that case made clear that the term "health plans" referred only to plans offered by a "health carrier," not a benefit plan offered by an employer, and defined "health carrier" to include only a disability insurer, a health care service contractor, or an HMO, and excluded employer-sponsored, self-funded health plans.

ii. Statutes Regulating Third Party Prescription Drug Programs

A number of states have enacted laws governing third party prescription drug programs, which involve payments for prescription drugs by third parties (not the patient), pursuant to agreements between pharmacies and the third party payor, for example, HMOs, PPOs, insurers, employers or other organizations. For various reasons, many of these programs are economically damaging to independent retail pharmacists by providing only for acquisition costs and a fixed dispensing fee, and they tend to raise pharmaceutical prices for those who are not covered by a third party program. A number of states have responded by enacting laws governing these programs. According to commentators, the laws

> primarily regulate third party prescription drug programs in three ways. First, ... [they] require that third party prescription drug agreements not establish reimbursement rates that are less than the prevailing rates paid by ordinary consumers for the same services. Second, they all require that every agreement include a formal payment schedule and precise rules on the cancellation of coverage to beneficiaries of the program. Third, they prohibit administrators of third party prescription drug programs to deny payment to any pharmacy for pharmaceutical services rendered because of the fraudulent use of prescription program identification cards.

Rindler & Miller, "Thoughts on a Faded Peacock: The Effect of ERISA's Preemption Provision on State Third Party Prescription Drug Program Statutes," 39 VAND. L. REV. 23 (1986).

Alabama's statute was challenged as preempted by ERISA, and the court concluded:

> The Pharmacy Act precludes employers and employees from structuring employee benefit plans that include third party prescription programs which call for reimbursement rates that "are less than the usual and customary rates paid by consumers not covered by a third party plan." Although the Act directly regulates the agreements and relationships between insurers and pharmacies, it effectively regulates what employers and employees can and cannot include in employee benefit plans. . . . Accordingly, the Act "relate[s] to" these plans and the Act is due to be preempted unless the Act fits within one of the exemptions listed in ' 514."

Blue Cross and Blue Shield v. Peacock's Apothecary, Inc., 567 F. Supp. 1258, 1267 (N.D. Ala. 1983)(emphasis added).

The district court concluded that:

> [t]he Pharmacy Act precludes employers and employees from structuring employee benefit plans that include third party prescription programs which call for reimbursement rates that "are less than the usual and customary rates paid by consumers not covered by a third party plan." Ala.Code ' 34-23-115 (Supp.1982). Although the Act directly regulates the agreements and relationships between insurers and pharmacies, it effectively regulates what employers and employees can and cannot include in employee benefit plans. The employee benefit plans of the fifty-one employer groups, which are involved in this action, all mandate reimbursement rates that violate the Act. Section 2 of the Act (' 34-23-111) makes explicit reference to employee benefit plans and defines "third party prescription program" to include employee benefit plans. Based on these facts, the court holds that the Pharmacy Act "has a connection with or reference to" the employee benefit plans of the fifty-one employer groups.

Id. at 1276.[5]

f. Conclusion

[5] Further research would be required to determine the extent to which other states third party prescription drug legislation has been preempted by ERISA.

The boundaries of ERISA preemption remain difficult to determine. The risks of preemption should be assessed more when specific legislative proposals are presented. However, the following general principles may be drawn from the cases:

Vermont pharmaceutical legislation may not:

- cause an administrator of a nationwide employee benefit plan to alter its plan to comply with Vermont law, i.e., subject the administrator to the risk of having to comply with inconsistent state regulations;

- invalidate a provision of an employee plan otherwise in compliance with federal law;

- in regulating insurance companies, define the practice of insurance in a way that includes employee benefit plans;

- require insurers and managed care plans to allow pharmacies willing to meet the terms of their prescription network plans to participate in those plans ("any willing provider"), even if the law exempts from the requirement self-insured employee benefit plans (Texas Pharm. Ass'n v. Prudential Ins. Co. of America);

- contain provisions that otherwise would be preempted by ERISA and save itself from preemption by including a provision that states that ERISA plans are exempt. (Mackey v. Lanier Collection Agency & Service, Inc.).

Vermont pharmaceutical legislation may:

- regulate insurance companies;

- establish rates that hospitals must charge for patient care based on average costs (not individual patient costs) and impose a surcharge on commercial insurers and HMOs, but exempt from the surcharge Blue Cross/Blue Shield because of their higher costs due to their open enrollment policies (New York State Conference of Blue Cross & Blue Shield Plans v. Travelers Ins. Co.); and

- have an indirect economic influence on choices made by ERISA administrators (Travelers).

2. Prescription Drug Marketing Act

The Prescription Drug Marketing Act, enacted as subsection (d) of Section 801 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. ' 381(d)), prevents any entity, other than the manufacturer, from importing pharmaceuticals which are manufactured in the United States and then subsequently exported to a foreign country, such as Canada. Stated otherwise, once the pharmaceutical products are exported from the United States, the federal statute prevents their importation by anyone other than the manufacturer. The law provides in pertinent part that:

> no drug subject to section 353(b) of this title [defining prescription drugs] . . . which is manufactured in a State and exported may be imported into the United States unless the drug is imported by the manufacturer of the drug.

This law therefore precludes private and public entities from purchasing drug products in Canada (which were manufactured within the U.S.) and reselling those products in the United States.

3. Price Disclosure

This part addresses a possible preemption challenge to legislation requiring manufacturers, wholesalers, or retailers to disclosure price information relating to their purchases and sales of prescription drugs.

Our research turned up no provisions of federal law that would expressly preempt Vermont from requiring price disclosure by manufacturers. Thus, a preemption argument by manufacturers would most likely be based on implied preemption. A court's assessment of whether the U.S. Congress impliedly intended to preempt state laws mandating pharmaceutical price disclosure would be based on its interpretation of federal statutes in the field.

We have identified two federal laws that involve pricing disclosure requirements placed on pharmaceutical companies. <u>First</u>, a provision of the Federal Property Acquisition Supply Act (FASA) requires manufacturers to submit information on the "non-federal average manufacturer price" and separately authorizes the Veteran's Administration to "audit the relevant records of the manufacturer or of any wholesaler that distributes the drug, and may delegate the authority to audit such records to the appropriate Federal agency ...." 38 U.S.C. ' 8126(e)(3). FASA requires that the information reported or obtained by audit "remain confidential." 38 U.S.C. ' 8126(e)(4).

<u>Second</u>, the Medicaid Drug Rebate Law (OBRA '90) requires manufacturers participating in the Medicaid program to provide information to the federal government regarding average manufacturer prices and the statutorily defined "manufacturer's best price". 42 U.S.C. ' 1396r-8(b)(3). The statute provides penalties for a manufacturer's failure to provide timely information or the provision of false information, and provides for surveys of wholesalers and manufacturers to verify the price information reported to the government. <u>Id.</u> Finally, the law

prohibits federal and state agencies from disclosing prices charged for drugs under the Medicaid statute "in a form which discloses the identity of a specific manufacturer or retailer." Id. [6]

Neither of these statutes appear to evidence a congressional intent that national uniform standards for drug price disclosure are necessary, nor an intent to occupy the entire field of drug price disclosure regulation. Rather, both statutes are targeted to facilitate federal programs involving the purchase of drugs under statutorily imposed pricing regimes; the price information is necessary to calculate the price at which the federal agency will purchase the drug from the manufacturer. As a result, the most likely candidate for an argument that Vermont price disclosure legislation is preempted by federal law would be based on an actual conflict between the state law and these federal laws.

Legislation requiring drug manufacturers and wholesalers to provide a state agency with price information, or allowing audits of wholesale prices, would appear to be consistent with FASA's and OBRA's requirements for disclosure of pharmaceutical prices. Such state legislation would impose requirements similar to those already imposed under federal law; indeed, state agencies administering Medicaid programs apparently already receive some of this information. In effect, the state would simply be requiring that the manufacturer share with a new entity information already provided to federal and state governments administering Medicaid and the Federal Supply Schedule.

On the other hand, a plausible preemption challenge to disclosure requirements could be made if the state legislation failed to include a provision designed to keep the price information disclosed confidential.

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[6] The statute provides:

> Confidentiality of information.
>
> Notwithstanding any other provision of law, information disclosed by manufacturers or wholesalers under this paragraph or under an agreement with Secretary of Veterans Affairs .... is confidential and shall not be disclosed by the Secretary or the Secretary of Veterans Affairs or a State agency (or contractor therewith) in a form which discloses the identity of a specific manufacturer or wholesaler, prices charged for drugs by such manufacturer or wholesaler, except -- (i) as the Secretary determines to be necessary to carry out this section, (ii) to permit the Comptroller General to review the information provided, and (iii) to permit the Director of the Congressional Budget Office to review the information provided.

42 U.S.C. ' 1396r-8(b)(3)(D).

Such a failure to protect the confidentiality of price information disclosed by report or audit may give manufacturers and wholesalers a viable argument that the disclosure requirement would be preempted by federal law because of an actual conflict. Federal law prohibits state agencies from disclosing price information in a form by which a specific manufacturers' prices would be revealed; state legislation without similar protections could be said to conflict with the federal prohibition.[7]

In enacting its PACE program, which includes provisions requiring that manufacturers disclose price information to the state, Pennsylvania legislators apparently recognized the potential conflict with federal law. The statute includes a confidentiality provision similar to the one found in federal law:

> (E) CONFIDENTIALITY OF INFORMATION.-- Information disclosed by manufacturers, wholesalers or direct sellers under this chapter is confidential and shall not be disclosed by the department in a form which discloses the identity of a specific manufacturer, wholesaler or direct seller or the prices charged for drugs by the manufacturer or wholesaler, except as the department determines to be necessary to carry out this chapter and to permit the Department of the Auditor General and the Office of State Inspector General to review the information provided.

72 P.S. ' 3761-704 (C-E).

To summarize, it appears that federal law would not preempt a state from requiring manufacturers and wholesalers to disclose price information as part of their participation in a pharmaceutical purchasing program. On the other hand, should the legislation not provide for company-specific drug price information to be kept confidential, the legislation may be vulnerable to a preemption argument.

4. Federal Procurement

a. Federal Scheme for Pharmaceutical Pricing

The prices that govern pharmaceutical purchases by federal government entities are derived, at least in part, from the non-federal average manufacturers price ("AMP"). The federal

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7 We were unable to locate any cases in which such a preemption argument was made. The lack of cases in which this issue was raised, however, should not be viewed as an indication that such a challenge would not be viable. There may be few states with price disclosure requirements, and those that do have such requirements may include confidentiality provisions similar to those in federal law. See main text, discussing PACE.

ceiling price is 76% of the AMP. The government may negotiate an FSS price that is lower than the federal ceiling, but the FSS formula may refer to the AMP.

FASA defines the AMP as the weighted average price of a single form and dosage unit of the drug that is paid by wholesalers in the United States to the manufacturer, taking into account any cash discounts or similar price reductions during that period, but not taking into account (a) any prices paid by the Federal Government; or (b) any prices found by the Secretary to be merely nominal in amount. 38 U.S.C. ' 8126(h)(5).

The interaction of state benchmarks and calculation of AMP may raise preemption issues. The AMP, federal ceiling and, possibly, FSS prices are based upon the prices that wholesalers throughout the country pay for pharmaceuticals. If states require pricing based upon the AMP or federal prices, the result may be that the AMP or federal price is based on the state price which is based on the federal price.[8] This circularity potentially makes it impossible to determine either price, frustrating both the federal and state laws.

Even if the calculation of the AMP would survive the adoption of state pricing schemes tied to the AMP or FSS, the result may be a downward spiral in prices. Assume, for example, that states adopt statutes requiring prices no greater than 90% of the most recently calculated AMP. The AMP for the next period would be lower. State prices then would be 90% of the lower AMP, which would result in an even lower AMP in the succeeding period. Even if the states tied prices to the full AMP, the AMP would serve as a cap and the AMP would decrease each year. The standard may, therefore, be practically unworkable.

To the extent that a Vermont benchmark would make the federal government's framework for calculating drug prices unworkable, a preemption argument may be available.

b. General Federal Interest in Procurement at Low Cost

The preemptive effects of federal procurement of pharmaceuticals could be a problem for legislation that uses the Federal Supply Schedule as a pricing benchmark, since the effect of such legislation could be to raise federal procurement costs. For example, if many states regulated drug prices at the FSS price, pharmaceutical companies may be less willing to sell at a discount to the federal government.

The Supreme Court has recognized a federal interest in not having its procurement costs increased as a result of state law in Boyle v. United Technologies Corp., 487 U.S. 500 (1988). Boyle involved a lawsuit brought by the father of David Boyle, a Marine helicopter copilot, who

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[8] It is unclear at this point whether the Vermont transactions would remain part of the calculation of AMP. Our understanding is that the Pennsylvania PACE program sales are not included in the AMP calculation. If this is the case then the result of all states adopting the benchmarks would be the inability to calculate AMP due to the lack of transactions for purposes of calculating the AMP.

was killed when his helicopter manufactured by the Sikorsky Division of United Technologies crashed off the coast of Virginia during a training exercise. Suit was brought under state tort law alleging defective design. The jury found the company liable for $750,000, and the company appealed, arguing that its procurement contract with the defense department precluded the state tort recovery.

The Supreme Court agreed with the company, holding that a verdict under state tort law for an alleged defect in the helicopter was preempted by federal procurement law when the specific "defect" was required to conform with the terms of the government contract.

The Court emphasized that preemption was appropriate because of the "uniquely federal interest" at stake. The unique interest arose from two factors. First, the case involved obligations to and rights of the United States under its contracts, which "are governed exclusively by federal law." 487 U.S. at 504. Second, the case involved the liability of independent contractors performing work for the Federal Government, which "like the liability of federal officials, is an area of uniquely federal interest." 487 U.S. at 505 n.1.

Further, the Court limited defense contractor tort immunity to limited circumstances:

> Liability for design defects in military equipment cannot be imposed, pursuant to state law, when (1) the United States approved reasonably precise specifications; (2) the equipment conformed to those specifications; and (3) the supplier warned the United States about the dangers in the use of the equipment that were known to the supplier but not to the United States.

Boyle, 487 U.S. at 512.

In language that, taken out of context, could be said to support a preemptive federal interest in not having states interfere in federal procurement by increasing costs, the Court said:

> The imposition of liability on Government contractors will directly affect the terms of Government contracts: either the contractor will decline to manufacture the design specified by the Government, or it will raise its price. Either way, the interests of the United States will be directly affected.

487 U.S. at 507 (emphasis added).

Boyle would seem to provide only weak support for a more general preemptive federal interest in procurement that might arise as a result of state legislation using the FSS as a benchmark. Boyle involved a military contract for a helicopter that was required to conform to specific guidelines. In purchasing pharmaceuticals, presumably the federal government acts as any purchaser, without imposing specific criteria upon manufacturers. Furthermore, the entire analysis in Boyle -- including the three-part test limiting its application -- pertains to immunity from tort liability, and not to preemption in general. Thus, the federal government's general interest in procuring goods at low cost is unlikely to have any preemptive effect on state use of a federal pricing benchmark, even if such use may raise federal procurement costs.

D. Federal Areas of Law Unlikely to Raise Preemption Issues

1. Medicaid Preemption

Preemption cases in the Social Security area relate primarily to state public funding statutes or to the methods for calculating Medicaid copayments or other aspects of state Medicaid programs themselves. Below are examples of the types of states laws that might be preempted by Medicaid. As currently understood, preemption is unlikely to occur under the regulatory schemes being considered by Vermont.

Two examples of cases where preemption has applied illustrate why preemption should be unlikely for generally applicable legislation designed to lower prescription drug prices:

- The Medicaid Act preempted in part an Arkansas law declaring that "[n]o public funds will be used to pay for any abortion, except to save the mother's life." The state could not prevent Medicaid money from being used to pay for abortions because federal law requires Arkansas and other states that participate in the Medicaid program to pay for abortions in cases where pregnancy is the result of rape or incest or when an abortion is necessary to save the mother's life. Dalton v. Little Rock Family Planning Servs., 516 U.S. 474 (1996).

- A federal appeals court held federal law preempted a North Carolina law limiting the amount medical providers can take from victim's successful tort claims to $1500. Cox v. Shalala, 112 F.3d 151 (4th Cir. 1997). The law was intended to protect accident victims from having their tort recovery diminished by health care providers. The federal government sought reimbursement under Medicare's secondary payer provisions for $181,187.75 it conditionally paid on the tort victim's behalf. It argued that the Medicare law preempted the state's Wrongful Death Act's $ 1,500 cap on a health care provider's right to recover damages. The court held that federal law preempted the $1500 cap and allowed Medicare to recover its expenditures.

In contrast, the following examples highlight the types of laws that have not been preempted.

- State laws limiting health care providers from "balance billing" -- charging in excess of Medicare reimbursement costs (which are limited by federal law to 15%, rachetted down from 25%) are not preempted. Downhour v. Somani, 85 F.3d 261 (6th Cir. 1996):

- States are not precluded from enacting legislation to protect Medicaid recipients. Solorzano v. Superior Court, 10 Cal. App. 4th 1135 (Cal App 1993) (observing that public health is a field historically within the police powers of the states).

- Medicaid did not preempt a state law creating license requirements for ambulances based on public convenience and necessity. Bell v. City of Mt. View, 66 Cal. App. 3d 332 (1977).

- A Florida law's requirement that Medicaid recipients pay a copayment for prescriptions, and automatically deducting the copayment from pharmacy reimbursements, was upheld against preemption challenge. Florida Pharmacy Ass'n v. Williams, 871 F. Supp. 1441 (N.D. Fla. 1993).

2. Drug Safety and Labeling Laws

a. Food, Drug and Cosmetic Act

The Federal, Food, Drug and Cosmetic Act includes no express preemption provisions. See 21 U.S.C., ' 301 et seq. The Act is primarily concerned with drug and food safety rather than market or pricing issues.

In general, a regulation relating to prescription costs will not conflict with the Food, Drug, & Cosmetic Act. A federal appeals court, for example, upheld a New York law requiring pharmacists to dispense generic drugs when authorized by a physician and when on a FDA list of bioequivalent drugs. The law mandated that the pharmacist "shall substitute a less expensive drug product containing the same active ingredients, dosage form and strength as the drug product prescribed." A group of pharmacists and physicians challenged the law, asserting it was preempted by the federal Food, Drug, & Cosmetic Act. The court concluded:

> The objective of the New York legislation is to regulate the sale of drugs to the limited extent of preventing the patient-consumer from being forced to pay the higher price of brand name drugs when less expensive generic equivalents are available and his physician is willing to permit use of the substitute. Determination of the safety and efficacy of the generic substitutes remains the function of the FDA.
>
> Thus there is no actual conflict between the federal and state statutes. The Generic Drug Act does not ban any FDA-approved drug and it does not frustrate Congress' purpose in enacting the

> Food, Drug, and Cosmetic Act, since the same federal agency (the FDA) still determines the safety and bioequivalency of generic substitutes that are furnished under the New York Act. Moreover, other state regulations not dealing with the safety or efficacy of drugs per se have been upheld. The federal statute is not so pervasive as to remove the states entirely from the field of drug regulation.

Pharmaceutical Soc'y of New York, Inc., v. Lefkowitz, 586 F.2d 953, 958 (2nd Cir. 1978)(footnote and citation omitted).

Other states have similar generic drug prescription laws.

b. Pharmaceutical Labeling

Various federal statutes regulate the labeling of prescription drugs, including the Fair Packaging and Labeling Act, 15 U.S.C. ' 1451 et seq. (prohibiting misleading labeling of all consumer products) and the Food, Drug and Cosmetic Act, 21 U.S.C. ' 301 et seq. (establishing minimum labeling requirements for prescription drugs). These statutes are unlikely to have a preemptive effect unless Vermont would pass labeling legislation that directly conflicts with federal requirements.[9]

Preemption depends largely on whether compliance with both federal and state law is possible. In Florida Lime & Avocado Growers, 373 U.S. 132 (1963), by a 5-4 decision the Supreme Court upheld a California statute that established a standard for avocado maturity based on oil content which served to bar the import into that state of Florida avocados that met the standards established in federal regulations. The majority concluded that "there is neither such actual conflict between the two schemes of regulation that both cannot stand in the same area, nor evidence of congressional design to pre-empt the field." The court also noted that there was no "physical impossibility" of complying with the federal and California standards. The federal standards were minimum standards and not "uniform" standards, the Court concluded.

3. Patent Law

Patent rights are generally subject to the right of states to legislate over matters of commerce and in the exercise of police powers. However, Vermont would be preempted from interfering with the patent owner's monopoly.

4. Federal Antitrust Laws

[9] Note, however, that a labeling requirement may be subject to a Commerce Clause challenge if the labeling requirements are particularly burdensome or contrary to other state statutes.

The Robinson-Patman Act forbids price discrimination unless it is based on differential costs or is intended to meet a competitor's price. The statute makes it "unlawful for any person ... to discriminate in price between different purchasers of commodities of like grade and quality... where the effect may be substantially to lessen competition or tend to create a monopoly." 15 U.S.C. ' 13(a). A plaintiff must prove a "competitive injury."

A preemption issue under the Robinson-Patman Act may arise in the following context: To the extent that state laws prohibit price discrimination, they may apply more stringently than the Robinson-Patman Act, raising a preemption issue. For example, the state law might not allow a "meeting the competition defense," which courts have recognized under Robinson-Patman, or they may not require a potential plaintiff to prove competitive injury.

Courts have been reluctant to find state antitrust laws preempted by federal antitrust laws even if the former apply more stringently than the latter. See, e.g., Exxon Corp. v. Governor of Maryland, 437 U.S. 117 (1978)(Maryland law barring vertical integration by petroleum refiners into retail service outlets not preempted by federal antitrust laws allowing vertical integration). One court held that a price discrimination statute covering fuel prices was not preempted by federal antitrust laws despite having a narrower "meet the competition" defense than the federal statute. Shell Oil Co. v. Younger, 587 F.2d 34 (9th Cir. 1978).

III. CONTRACT CLAUSE

The Contract Clause is a potential concern for a number of the proposals under consideration by the Committee. Retailers, wholesalers, and manufacturers have existing contracts that could be adversely affected, depending on the proposal ultimately decided upon by the Committee. The legislative proposals may therefore implicate the Contract Clause. This part provides an overview of the Contract Clause and explains how it may intersect with the types of proposals under consideration.

A. Overview of Contract Clause

The Contract Clause provides, in relevant part, that "[n]o State shall ... pass any ... Law impairing the Obligation of Contracts". U.S. Const. art. 1, ' 10, cl. 1.

A violation of the Contract Clause depends on whether the state law (1) causes a substantial impairment of a contract; (2) promotes a significant and legitimate public purpose; and (3) is reasonably tailored to promoting the legitimate public purpose.

A party challenging state legislation as in violation of the Contract Clause would therefore first be required to show that the law substantially impairs its contracts. If a court would agree that the law substantially impairs existing contracts, the challenger would have to show that the law does not advance a legitimate public purpose or that the law is not reasonably adapted to the advancing that purpose. We next consider in more detail the three steps of Contract Clause analysis.

1. Substantial Contractual Impairment

This first requirement for a violation of the Contract Clause -- that the contract be substantially impaired by the state law --- includes three subparts, all of which must be exist: (a) the existence of a valid contract, (b) a change in the state law that impairs that contract, and (c) the impairment must be substantial. General Motors Corp. v. Romein, 503 U.S. 181, 185 (1992).

The first subpart is a question of state law, which governs the formation of contracts. It also suggests that the Contract Clause applies only retroactively, to existing contracts. Legislation impairing contractual relations that are contemplated for the future would fail this first requirement. Additionally, it is likely that under state contract law an opportunity to renew a contract means that the contract is not in existence until the renewal option is exercised. Because a contract cannot be in existence until the renewal clause is exercised, the Contract Clause would be rendered inapplicable if the renewal option is not exercised before the legislation impairing the contract becomes effective. However, a party might argue that a renewal right is granted by the underlying contract, and a state law making that renewal right less valuable could be seen as interfering with the contract.

The second component -- a change in state law -- is self-explanatory.

The third component -- the substantiality requirement -- requires further analysis. To be substantial, the impairment of the contract must be more than technical. "Minimal alteration of contractual obligations may end the inquiry at its first stage." Allied Structural Steel Co. v. Spannaus, 438 U.S. 234, 245 (1978). Courts will consider whether the contracting parties specifically relied on the contractual term which the state legislation affects when they entered into the contract. If the contractual provision is "the central undertaking" or "primary consideration" of the parties, the reliance placed on the provision by the parties will weigh in favor of a finding of substantiality. City of El Paso v. Simmons, 379 U.S. 497, 514 (1965).

Laws that have been upheld against contract clause challenges, in part because they did not impair a central aspect of the contract impaired, include the following:

- a state law eliminating the use of escalator clauses in natural gas contracts (Energy Reserves Group, Inc. v. Kansas Power & Light Co., 459 U.S. 400, 415-16 (1983);

- a law lowering the interest rate and delaying the maturity date in bond contracts (Faitoute Iron & Steel Co. v. City of Asbury Park, 316 U.S. 502, 504 (1942));

- a law placing limits on a previously unlimited property right to reinstate ownership of land after default on a loan (City of El Paso, 379 U.S. at 515);

- a law modifying bond contracts for a water utility to eliminate the right to impose liens on property owners for the unpaid bills of their tenants, when other remedies were available and only a small group of people were affected (City of Charleston v. Pub. Serv. Comm'n of West Virginia, 57 F.3d 385, 394 (4th Cir. 1995)).

On the other hand, a state law that effects "a fundamental change" in a contract will be more likely to be found to be substantial. See Spannaus, 438 U.S. at 246. For example, the following laws were found to "substantially" impair contracts:

- a law requiring that companies with pre-existing pension plans pay pension benefits at termination of the plan or plant closing to employees who had worked ten years regardless of the specific provisions in the pension contract (Spannaus);

- a state law requiring mining companies to leave enough coal in the ground so that the surface land remained undamaged, or to repair damaged surface land, when specific contractual provisions between surface owner and mining company waived liability for such damage (Keystone Bituminous Coal Ass'n v. DeBenedictis, 480 U.S. 470 (1987);

- a city furlough, passed in response to severe budget shortfalls, lowering the annual pay for city employees by the annual equivalent of 2.5 days. (Baltimore Teachers Union v. Mayor & City Council of Baltimore 6 F.3d 1012, 1018 (1993) ("In the employment context, there likely is no right both more central to the contract's inducement and on the existence of which the parties more especially rely, than the right to compensation at the contractually specified level.").

Another factor considered in determining whether a particular impairment is substantial is the extent that the subject matter of the contract has been regulated by federal or state laws. This factor presumes that parties who know the subject matter of their contract is regulated cannot rely on the absence of new regulation governing the subject matter of their contract. For example, in Energy Reserves, supra, a public utility contracted with a natural gas supplier for gas supplies at a price set by contract. An escalator clause provided that the price could be raised according to the highest price fixed by the government. Congress passed the Natural Gas Act which would have afforded the supplier a higher price under the escalator clause, but Kansas enacted a law that effectively precluded the supplier from using the escalator clause to its fullest extent. There was no impairment because at the time of contracting the supplier knew natural gas was subject to both state and federal regulation. 459 U.S. at 410.

2. Legitimate Public Purpose

If the state law substantially impairs contracts, the next step in the Contract Clause inquiry asks whether the state law seeks to fulfill a legitimate public purpose.

The Supreme Court has frequently acknowledged that although the language of the Contract Clause is facially absolute, it is generally subservient to the general police powers of the state to advance the general welfare of its citizens. See Exxon Corp. v. Eagerton, 462 U.S. 176, 190 (1983). If the Contract Clause were interpreted broadly, the Court has acknowledged, "one would be able to obtain immunity from state regulation by making private contractual arrangements." United States Trust Co. v. New Jersey, 431 U.S. 1, 22 (1977). The constitutional prohibition against contract impairment therefore "must be accommodated to the inherent police power of the State to safeguard the vital interests of its people." Exxon, 462 U.S. at 191.

The Court has recognized a state's interest in protecting consumers from price increases as a legitimate public purpose behind laws impairing contracts. In two of its more recent cases involving Contract Clause challenges to state regulation, the Supreme Court expressly recognized a state's interest in protecting consumers as a "significant and legitimate" state interest. See Energy Reserves, supra; Exxon Corp., supra. In Exxon Corp., the Supreme Court addressed an Alabama law increasing the severance tax for oil and gas from Alabama wells and prohibiting producers from passing the tax on to purchasers. The producers argued that the pass-through provision prevented them from taking advantage of specific contractual clauses allowing them to pass through cost increases. The Court concluded that the Alabama law advanced the "broad societal interest" of "protecting consumers from excessive prices." Exxon Corp., 462 U.S. at 191. In Energy Reserves, described supra, the Court stated:

> To the extent, if any, the Kansas Act impairs ERG's contractual interests, the Kansas Act rests on, and is prompted by, significant and legitimate state interests. Kansas has exercised its police power to protect consumers from the escalation of natural gas prices caused by deregulation. The State reasonably could find that higher gas prices have caused and will cause hardship among those who use gas heat but must exist on limited fixed incomes."

459 U.S. at 416-17.

Another factor the Supreme Court has applied in weighing the sufficiency of the public purpose of laws impairing contracts involves the distinction between laws that apply broadly and those that apply particularly to contracting parties. For example, in Exxon Corp. supra, the court emphasized that the Alabama law

> did not prescribe a rule limited in effect to contractual obligations or remedies, but instead imposed a generally applicable rule of

> conduct .... The prohibition applied to all oil and gas producers, regardless of whether they happened to be parties to sale contracts that contained a provision permitting them to pass tax increases through to their purchasers. The effect of the pass-through prohibition on existing contracts that did contain such a provision was incidental to its main effect of shielding consumers from the burden of the tax increase.

462 U.S. at 191-92 (citations omitted; emphasis added). See also, e.g., Wisconsin Central Limited v. Public Serv. Comm'n of Wisc., 95 F.3d 1359, 1371 (7th Cir. 1996)(state law setting compensation for utility use of railroad rights-of-way upheld in part because it was generally applicable rule of conduct, applicable regardless of any particular contracts it affected). In contrast, the Minnesota statute struck down by the Court in Spannaus, supra, applied only to private employers that had contracts with employees, requiring them to pay additional benefits, beyond those it had agreed to provide in the contract if they terminated the pension plan or closed a Minnesota office. In other words, the statute operated exclusively to alter contractual duties.

A final consideration relates to the contracting parties. When state or local laws affect contracts to which the lawmaker is a party, courts apply more scrutiny to the alleged governmental interest in enacting the legislation. See Continental Ill. Nat'l Bank & Trust Co. v. Washington, 696 F.2d 692, 701 (9th Cir.) ("Because the State is a contracting party, we give less deference to its claims of justification for impairment.").[10]

3. Relation Between State Law and Public Purpose

The last component of the test for invalidity under the Contract Clause seeks to determine whether the state law is a reasonable means of advancing the legitimate interest identified in the second prong of the analsyis. This component requires assessing the extent to which the component of the legislation impairing contracts is necessary to furthering the state's interest. If the interest clearly could be served without the provision impairing contracts, the law could be invalidated under this tier of the test.

In examining the relationship between the state law and the interest it serves, however, courts will generally defer to the judgment of the state legislature so long as it is reasonable. See, e.g., Energy Resources, 459 U.S. at 418 ("Nor are the means chosen to implement these purposes deficient, particularly in light of the deference to which the Kansas Legislature's judgment is entitled.")(emphasis added). In Energy Resources, the Supreme Court concluded that the Kansas law precluding a gas supplier from using an escalator clause in a contract to pass

[10] Even in such cases, however, courts still may defer to the law so long it is reasonable. See, e.g., Baltimore Teachers Union, 6 F.3d at 1016 (1993)(upholding decision by City of Baltimore to lower pay for city employees in response to budget constraints).

on price increases was a reasonable means of promoting the state's interest in protecting consumers from price increases. In another case, the Court concluded that a state legislature could reasonably find that requiring mining companies to leave undamaged surface land or repair damage was reasonably tailored to the objective of avoiding or requiring repair of environmental damage caused by mining. Keystone Bituminous Coal Ass'n, supra. Compare United States Trust Co. v. New Jersey, 431 U.S. 1 (1977)(applying a less deferential standard of review because legislation altered a public contract and invalidating a statute reneging on a state commitment to bondholders not to subsidize unprofitable rail operations with bond revenues when there were more reasonable alternatives for the goal of improving commuter service).

B. Legislation Placing a Ceiling on Prices Lower Than Those Allowed in Existing Contracts

A number of the legislative proposals under consideration, if applied to existing contracts, could render unlawful existing prices established in contracts between manufacturers, wholesalers, or retailers. The discussion below assumes that the legislation is drafted to apply to existing contracts, so as to raise Contract Clause issues. The potential problems identified would be avoided if the legislation affected prospective contracts only. The analyses that follow track the basic four-part test described above for whether a law violates the Contract Clause.

1. Substantial Contract Impairment

A safe assumption is that legislation that alters the price in existing contracts impairs those contracts, because it prevents the seller from receiving the benefits of the higher contract price.

Price is a central feature of any sales contract. Like the state law in Spannaus that required employers to pay pension benefits in spite of contrary contractual provisions, a law changing prices in existing contracts is likely to be viewed as substantial. Indeed, like an employment contract, in a sales contract "there likely is no right both more central to the contract's inducement and on the existence of which the parties more especially rely, than the right to compensation at the contractually specified level." Baltimore Teachers Union, 6 F.3d at 1018.

In sum, as a result of the central feature of price in a sales contract, a law rendering unlawful the prices of existing contracts is likely to be viewed as substantially impairing those contracts.

2. Legitimate Public Purpose

The purpose behind legislation affecting prices in existing contracts -- making prescription drugs affordable for citizens of the state -- may be viewed as a sufficiently important public purpose for purposes of Contract Clause analysis. The legislative effort to provide lower pharmaceutical prices for Vermont citizens is analogous to two of the Supreme Court's more recent cases involving Contract Clause challenges to state regulation, where, as noted above, the Supreme Court expressly recognized a state's interest in protecting consumers as a "significant and legitimate" state interest.

Vermont's action mandating price changes would have the goal of enhancing the general health and welfare of Vermont citizens by making prescription drugs more affordable. Like the Kansas law examined in Energy Resources, Vermont legislators reasonably can conclude that high prescription drug prices "have caused and will cause hardship" of Vermont citizens who need pharmaceutical products "but must exist on limited incomes."

Energy Resources and Exxon Corp., however, did not address an alteration of the basic price of contracts, but the application of a contractual provisions allowing that price to incrementally change. We cannot predict how this difference may affect a court's analysis.

Vermont also could argue that it has a legitimate state interest in that the price regulation presumably would apply to all manufacturers and wholesalers subject to the regulatory regime or prescription drug program, regardless of whether such contracts are in existence or not. Thus, it would constitute a generally applicable rule of conduct analogous to the Alabama law at issue in Exxon Corp., and for that reason it would support a judicial finding that the statute furthers a legitimate state interest.

Finally, a third factor weighing in the state's favor is that the contracts affected by the legislation would be private contracts rather than contracts involving government subdivisions. Since the Vermont legislation would not serve to negate any contracts to which the state was a party, a court may apply less scrutiny to the legislature's assertion of the interest it seeks to promote through the impairment of contracts.

3. Relation Between State Law and Public Purpose

It is unclear how legislation rendering price provisions in existing contracts would withstand an argument that it is not reasonably tailored to the goal of protecting consumers from price increases. Such legislation would cause greater contractual impairment than the legislation preventing the use of escalator or pass-through clauses in contracts, as in Energy Resources and Exxon. Moreover, although courts are generally deferential to legislatures' choices, an obviously less burdensome alternative would be to draft legislation to apply prospectively only, thereby saving existing contractual prices from being unlawful.

Since we are informed that most pharmaceutical contracts expire in less than five years, saving the price provisions in existing contracts from being rendered unlawful may not significantly impede the efficacy of legislation regulating prices. As a result, a court could conclude that the legislation applicable to existing contracts is not reasonably tailored to its goal of protecting Vermont consumers of prescription drugs.

4. Conclusion

It is difficult to predict how a court would rule on legislation rendering prices in existing contracts unlawful. It is likely that a court would find such legislation to cause a substantial impairment to affected contracts. While a court may also find that the legislation serves a legitimate public purpose, it may be unlikely to find such legislation reasonably tailored to that purpose, particularly given the alternatives available that would not cause such impairment. In order to avoid the uncertainty, it would be advisable to include in any legislation a provision saving the price provisions of contracts in existence at the time legislation is passed.

C. Price Disclosure Legislation Affecting Existing Contracts

1. Introduction: Industry Contracts Potentially Implicated

In order to implement pharmaceutical pricing legislation, the state may find it necessary to require drug manufacturers and wholesalers to provide pricing information. In particular, in order to establish appropriate prices, the state may want access to price information from contracts between drug manufacturers and other purchasers, including information about rebates and other discounts given large buyers.

This section considers the strength of a claim by manufacturers that disclosure requirements violate the Contract Clause by impairing present contracts with purchasers, many of which include non-disclosure provisions.

Provisions prohibiting the disclosure of prices are a standard feature in many contracts between large purchasers of pharmaceuticals and manufacturers.[11] These provisions generally preclude disclosure of the amount of any discounts or rebates the manufacturers is providing the purchaser. Statutory disclosure requirements under consideration may require manufacturers or purchasers to disclose to a Vermont agency or regulators the amount of the rebates/discounts protected from disclosure in these contracts. To the extent that these disclosure requirements affect these contractual provisions, the parties to the contracts might contend that the disclosure provisions are unconstitutional because they violate the Contract Clause of the federal constitution.

Price disclosure legislation could be drafted in one of three ways. It could apply to (a) existing contracts, (b) new contracts; or (c) to new contracts and to contracts with renewal rights. As discussed above, laws with a prospective effect on contracts will not violate the Contract Clause; therefore scenarios (b) and (c) are unlikely to create a Contract Clause problem. The discussion in this part therefore focuses on scenario (a).

2. Contractual Impairment

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[11] A complete analysis would require viewing the contracts that would alleged be impaired by the Vermont legislation.

This discussion assumes the existence of a contract. However, whether a drug manufacturer or wholesaler can demonstrate that Vermont drug price disclosure legislation impairs nondisclosure provisions in its contract (the second part of the test for substantial impairment test) depends on the details of the legislation enacted. Because many drug manufacturers and wholesalers are already required to disclose price information to federal and state governments as part of their participation in Medicaid and the Federal Supply Schedule, Vermont may have a viable argument that a disclosure provision would not impair any existing contract.

This argument may depend in part on whether the particular contractual provisions mandating non-disclosure are made subject to state and federal disclosure requirements. See City of Charleston v. Pub. Serv. Comm'n of West Virginia, 57 F.3d 385, 392 (4th Cir. 1995) (concluding that, because contracts included provisions stating they were subject to the requirements of state law, that "it well may be that the bond contracts at issue here were not impaired at all").

Assuming Vermont disclosure regulation would impair (at least technically) the contractual provisions mandating nondisclosure, a court would apply a more thorough analysis to determine if the impairment was substantial. This issue is discussed next.

3. Substantiality

Vermont could point to several reasons why a price disclosure requirement would not cause a substantial impairment of a contract. The state may contend, for example, that the price disclosure provision is merely a technical provision in a contract the central purpose of which is the sale of goods and services. Arguably, a price nondisclosure provision in a sales contract for prescription drugs is not a central provision of a sales contract and is analogous to an escalator clause or passthrough provision in a contract for gas, as in Energy Reserves. See also Exxon Corp., supra (upholding state law prohibiting producers from passing a severance tax on to purchasers through a pass-through provision of a contract). Moreover, unlike Spannaus or Baltimore Teachers Union (and legislation rendering contractual prices unlawful, as discussed immediately above), price disclosure legislation would not alter the primary financial obligations of one of the parties to the sales contract.

Moreover, particularly if the legislation includes confidentiality provisions (such as those in the Medicaid Drug Rebate Law and PACE) prohibiting the disclosure of manufacturer-specific prices, the contracting parties' reason for including a nondisclosure provision in their contract -- presumably to prevent competitors and other customers from gaining access to manufacturer-specific prices -- would not be undermined through confidential disclosure to a state agency. Rather, the disclosure requirement would merely effect a technical violation of the contract not affecting the intentions of the parties.

Finally, the disclosure requirement may not be substantial due to existing state and federal laws requiring price disclosure (See discussion immediately preceding). Also, a court may conclude, as in Energy Resources, that pharmaceutical manufacturers and wholesalers may not reasonably rely on a nondisclosure provision when federal law mandates that manufacturers and wholesalers disclose the same information to federal and state agencies if they participate in the Medicaid program.

4. Legitimate Public Purpose

Assuming, for purposes of argument, that price disclosure requirements would substantially impair contracts between manufacturers and large purchasers, the next step in the Contract Clause inquiry asks whether the state law seeks to fulfill a legitimate public purpose.

Price disclosure requirements, established as part of a state's effort to keep pharmaceutical prices affordable, may be viewed as a sufficiently important public purpose overriding any concern over contractual impairment, for at least three reasons.

First, Vermont's statutorily mandated drug price disclosure requirements would be a part of a legislative effort to provide lower pharmaceutical prices for Vermont citizens. As noted above, a state's interest in protecting consumers has been recognized as a significant state interest. Second, like price regulation, price information disclosure requirements would apply to all manufacturers and wholesalers subject to the regulatory regime or prescription drug program, regardless of whether they have contracts that include nondisclosure provisions. And third, as noted above, the contracts affected are private contracts rather than government contracts.

5. Relation Between State Law and Public Purpose

Vermont legislation mandating price disclosure would likely withstand an argument that it is not reasonably tailored to the goal of protecting consumers from price increases. Such legislation would appear to cause less contract impairment than the legislation preventing the use of escalator or pass-through clauses in contracts, as in Energy Resources and Exxon, and significantly less than laws directly declaring unlawful contract prices. As a result, a court may view it as being narrowly drafted to avoid rendering unlawful a central feature of a contract.

Moreover, it would be difficult to administer a pharmaceutical program without such price information, as is made evident by federal and other state statutes relating to the procurement of pharmaceuticals. A court therefore would be unlikely to conclude that disclosure measures were unreasonable, particularly given the court's deference to the legislature's judgment. However, if the legislation did not include provisions for confidentiality, as discussed above, the state may need to explain why the goal of lowering pharmaceutical prices through the program needs to allow for the possibility of public dissemination of manufacturer- or wholesaler-specific pricing information.

6. Conclusion

Legislation requiring manufacturers and wholesalers of pharmaceuticals to disclose their prices as part of a program designed to lower prices for Vermont citizens would likely withstand Contract Clause scrutiny. There are three mains reasons: (1) other laws already impose such requirements on pharmaceutical companies, (2) the contractual non-disclosure provisions are unlikely to be considered a central aspect of the sales contracts, and (3) the requirements would further a legitimate and significant state interest in making pharmaceuticals more affordable for Vermont citizens.

Parties to contracts with nondisclosure provisions may be able to make a slightly stronger Contract Clause argument for invalidity should the Vermont legislation fail to include confidentiality provisions like those contained in federal pricing disclosure laws.

IV. TAKINGS CLAUSE

A. Overview

The Takings Clause provides that private property "shall [not] be taken for public use, without just compensation." U.S. Const. amend. 5. The Takings Clause protects legitimate, investment-backed expectations of property owners from diminution of the value of their property by government action. The determination of whether there is a legitimate expectation is a fact-based, "ad hoc" analysis which takes into account the "economic impact of the regulation on the claimant and, particularly, the extent to which the regulation has interfered with distinct investment-backed expectations." Penn Central Transportation Company v. New York, 438 U.S. 104, 124 (1978).

The Takings Clause does not require price regulators to use any particular formula so long as the end result is fair. If the end result of the price regulation is reasonable, that is sufficient for constitutional purposes, even if it is not profitable in every aspect. Proper considerations for setting rates for a public utility include whether the utility has enough revenue for operating expenses and the capital costs of the business. Federal Power Comm'n v. Hope Natural Gas Co., 320 U.S. 591, 605 (1944). Public utilities are entitled to earn a return on property employed for public use at a rate equal to that of other business facing similar risks. Bluefield Water Works & Improvement Company v. Public Service Comm'n, 262 U.S. 679, 692 (1923).

Finally, when price setting requires a factual analysis, a hearing may be required. (See discussion of procedural due process requirements.)

The Takings Clause does not forbid the governmental taking; it only requires that private property owners be reasonably compensated should a taking occur.

B. General Illustrations

Penn Central Transportation Co. v. New York City, 438 U.S. 104 (1978), is a leading Takings Clause case in which the Supreme Court declared that no taking occurred. The owners of New York's Grand Central Terminal sought approval to build an office tower on top of the terminal. A city law required designated landmarks (including Grand Central) to maintain their exteriors in good repair and to obtain the city's permission before making changes to the exterior. The city denied Grand Central permission to build because the office tower would ruin the aesthetic quality of the Terminal's "flamboyant Beaux Arts facade." The Court rejected the takings claim, reasoning that the restriction was comparable to general zoning legislation and that the denial did not prevent the Terminal from other uses of its property.

In Nollan v. California Coastal Comm'n, 483 U.S. 825 (1987), the Court found a taking requiring compensation. Beachfront property owners in California wanted permission to build a larger house to replace their existing smaller home. The state conditioned its permission on the landowner's agreement to allow the public to cross the landowner's beach, which was located between two beaches accessible to the public. The Court reasoned that the state's condition did not serve a public purpose related to the permit requirement and therefore required compensation.

In Ruckelshaus v. Monsanto Co., 467 U.S. 986 (1984), the Court found that trade secrets constituted property, the taking of which required compensation. The Environmental Protection Agency required manufacturers of pesticides to disclose their formulas and methods in order to gain permission to market their products; the formulas and methods would then be generally available to the public. The Supreme Court held that trade secrets qualified as property for purposes of the Takings Clause. Owners of trade secrets, however, only have a Takings Claim if they can show that they have a reasonable, investment-backed expectation that the information will not be disclosed. A statute providing for protection of trade secrets is sufficient to create a compensable expectation.

A final general example is 20th Century Insurance Co. v. Garamendi, 878 P.2d 566 (Cal. 1994), cert. dismissed, 115 S.Ct. 1085 (1995), where the California Supreme Court concluded that no compensation was required. At issue was a California law instituting auto insurance rate reductions pursuant to a state ballot initiative. The state high court held that "the inability to operate successfully is a necessary -- but not a sufficient -- condition of confiscation." The court said the company may pursue rates sufficient to earn an adequate return on its investment, but such rates are "not a right that it can demand."

C. Illustrations Involving State Price Setting

In Duquesne Light Co. v. Barasch, 488 U.S. 299 (1989), the Supreme Court addressed the decision of Pennsylvania regulators to disallow a utility's full cost recovery of a nuclear plant that had been abandoned, even though the regulators had found that the decision to begin constructing the plant, as well as the decision to abandon the plant, were prudent decisions. The

Court concluded that no taking had occurred because the "end result" of the denial of full cost recovery was not confiscatory.

In Bluefield Water Works, supra, however, the Court found that the rates set were confiscatory. A rate of return of under six percent was too low to constitute just compensation for the use of property employed to render services. The Court concluded that low and irregular income would hurt the prices of securities of the utility and cause higher rates of return demanded by investors.

The Supreme Court has held that rates based on average regional costs are not confiscatory. Permian Basin Area Rate Cases, 390 U.S. 747, 769-70 (1967). The Court in Permian Basin held that the Federal Power Commission (FPC) could establish rates for gas producers based on regional average costs, rather than the cost of each individual producer. The Court observed that FPC procedures also allowed individual producers to seek "special relief."

D. Implications of Legislation Establishing Pharmaceutical Prices

At a minimum, any legislation establishing maximum prices for which an entity can sell pharmaceuticals within the state should comply with the Supreme Court's cases involving rate-setting by state public utility regulators. For example, while the entity affected by the price-setting would not have to earn a return on all aspects of its investment, the end result of the price setting could not be confiscatory. A total return of less than six percent may be considered too low. The legislation, or the agency administering the legislation, may be able to base prices based upon regional averages without incurring liability in a takings claim.

Beyond these general observations, it is premature to assess the viability of a takings claim by a manufacturer, wholesaler or retailer of pharmaceuticals. Once more details of the legislative proposals further analysis may be possible. As noted above, however, takings analysis is "ad hoc," based largely on the particular facts of the industry and the parties challenging the state action. As a result a complete analysis may require significant input from an expert in the economics of the pharmaceutical industry.[12]

V. DUE PROCESS CLAUSE

A. Overview

[12] Furthermore, we have not researched whether takings issues arise with respect to state laws mandating price disclosure. As noted above, the Supreme Court has held that trade secrets constitute property interests that may be "taken" by state action and for which compensation is required. Ruckelshaus v. Monsanto Co., 467 U.S. 986 (1984). We have not researched whether prices also constitute property that can be taken.

The Due Process Clause of the 14th Amendment prohibits a state from "depriv[ing] any person of life, liberty, or property, without due process of law." The Due Process Clause can apply to state pharmaceutical pricing legislation in two ways: as a limit on the state's "jurisdiction", or "reach", and as protection against arbitrary or inadequate procedures.

1. Jurisdictional Implications of Due Process

The Due Process Clause limits the power of the states to exercise jurisdiction over out-of-state persons. If there is insufficient connection, or "nexus," between the state and the person, the Due Process Clause prohibits the state from regulating that person's behavior.[13]

A state action satisfies due process if the person whom the state wishes to regulate has the "minimum contacts with the [state] such that the maintenance of the suit does not offend traditional notions of fair play and substantial justice." International Shoe Co. v. Washington, 326 U.S. 310, 316 (1945) (quoting other sources) (emphasis added). "Fair play" and "substantial justice" require that the person's contact with the state is substantial enough that it is "reasonably foreseeable" that the state will regulate the person.

Due process does not require physical presence. If a business located outside the state purposefully avails itself of the benefits of an economic market in the state, the state may regulate the business without violating the Due Process Clause. Quill Corp. v. North Dakota, 504 U.S. 298 (1992).

In Quill, the facts of which are described above in Part One: I.B.1.c, the Supreme Court held that the retailer's continuous and widespread solicitation of business within North Dakota was sufficient for the state to exercise its jurisdiction without violating the Due Process Clause.[14]

In contrast, in Helicopteros Nacionales de Colombia v. Hall, 466 U.S. 408 (1984), the Court held there were insufficient contacts for the court to exercise jurisdiction. A helicopter owned by a Colombian company crashed in Peru, killing four employees who were U.S. citizens. The employee's representatives sued the company in Texas. The company's contacts with Texas included: a company executive had gone to Texas to negotiate a contract, the company purchased helicopters from a Texas company, and it had pilots and service personnel trained in Texas. The contacts were insufficient because the claims asserted against the company did not arise out of, and were unrelated to, the company's Texas activities.

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[13] The Commerce Clause, distinct from the Due Process Clause, also requires a "nexus" between the state and the entity the state wishes to subject to its jurisdiction, as explained in Part One, I.B.1.b.

[14] The State's exercise of jurisdiction did violate the Commerce Clause, as discussed in Part One: I.B.1.c.

2. Procedural Due Process

Courts have interpreted the Due Process Clause to require procedural protections before a state may regulate behavior in a way that impairs one's life, liberty or property interest. When a state action affects the property interests of a general class of persons -- for example, by passing a statute -- the legislative process itself generally provides the process "due." But when a state action affects a discretely defined set of interests based on individual facts, the Due Process Clause requires greater procedural protections.

When states take action that affect individual property rights, courts will consider the extent to which the state has employed the following types of protections: notice to the adversely affected party, the use of a neutral decisionmaker; the opportunity to be heard orally and/or present evidence; the opportunity to be represented by an attorney; and whether there was a written decision and a statement of the reasons for the decision.

In determining the extent of protection required (i.e., what process is "due"), the courts consider the factual circumstances of the adverse government action. In particular, courts consider the following three factors: (1) "the private interest that will be affected by the official action;" (2) "the risk of erroneous deprivation of such interest through the procedures used, and the probable value, if any, of additional or substitute safeguards;" and (3) "the Government's interest, including the function involved and the fiscal and administrative burdens that the additional or substitute procedural requirement would entail." Mathews v. Eldridge, 424 U.S. 319, 335 (1976).

One of the Court's leading procedural due process cases involved a state's termination of an individual's welfare benefits. Goldberg v. Kelly, 397 U.S. 254 (1970). The Court held that a state must provide a hearing before an impartial decisionmaker before termination. The Court noted, however, that the hearing need not have all the full protections available to litigants at a trial, and the state need not provide the individual a lawyer.

In contrast, the Court ruled that a trial-type hearing was not required before a state terminated an individual's disability benefits when the individual receives notice of termination, access to information, an opportunity to submit a written statement before termination, and access to an evidentiary trial after termination. Mathews v. Eldridge, supra.

B. Jurisdictional Implications of Legislative Proposals

Because the standard for exercising jurisdiction under the Commerce Clause is higher than the Due Process Clause, challenges to Vermont's authority to exercise jurisdiction over businesses in the pharmaceutical industry are likely to focus on the Commerce Clause and not the Due Process Clause. To the extent that the Due Process Clause may apply, most pharmaceutical manufacturers and wholesalers over whom Vermont may wish to exercise jurisdiction will engage in sufficient activities in Vermont for the state to exercise jurisdiction. These activities include, for example: sales representatives making visits; advertising in the state;

some direct sales in the state, such as hospitals, HMOs or PBMs; and returned goods policies (in which manufacturers oblige themselves to pay for products not sold by the retail pharmacy, giving therefore manufacturer has a stake in the sales made in the state).

C. Implications of Legislation Establishing Pharmaceutical Prices

Should Vermont enact legislation with a mandatory price-setting component without any procedural protections for those affected, a court may conclude the entity's procedural due process rights have been affected. Without an opportunity to be heard and present evidence regarding appropriate prices, an affected entity may contend that the price set is arbitrary.

For example, if a mandatory price was established by reference to the FSS, a manufacturer or wholesaler may complain that FSS prices reflect lower costs related to the ease of selling large quantities of drugs through a federal program. Because Vermont legislation would have different characteristics, the manufacturer or wholesaler's costs will arguably be different. The entity may need to deal with many different buyers at the established price.

Under the Mathews v. Eldridge test, the regulated entities could argue that the private interest affected by the price-setting would be significant, going to the heart of the manufacturer or wholesaler's interest -- its revenues, and while Vermont's burden in adopting administrative procedures may be significant, depending on the details of the legislation and in particular how the price is set, the entities may have a strong argument that the risk of erroneous deprivation without some sort of hearing is significant.

It is difficult to predict how a procedural due process challenge to price-setting legislation would hold up in the courts without more details on how prices would be established and how they would change over time. There are risks, however, in enacting price-setting legislation without affording the regulated entities the opportunity to a hearing where evidence can be offered as to what the appropriate price should be.

PART TWO: APPLICATION OF LEGAL PRINCIPLES TO LEGISLATIVE PROPOSALS

This section applies the legal principles discussed in Part I to specific proposals under Committee discussion. These proposals include:

- Regulation of Manufacturers' Prices Where the Sale Takes Place Outside Vermont
- Regulation of Wholesale or Retail Transactions Where the Sale Takes Place Within Vermont
- State as Buyer and Reseller of Pharmaceuticals
- State as Program Administrator of Drug Discount Plan
- Requirement of "Best Price" or Nondiscrimination

For each proposal, we summarize the key features as we understand them, and then present an analysis. The legal basis for most of these analyses was already set forth in Part One. The analysis in this Part therefore consists of a direct and concise application of the legal principles to the specific program features listed. Although features of various proposals will change as Committee discussion continues, the analysis set forth in Part One will likely be readily applicable.

I. REGULATION OF MANUFACTURERS' PRICES WHERE THE SALE TAKES PLACE OUTSIDE VERMONT

A. Features

This approach would seek to regulate the price of sales by manufacturers where the sale takes place outside Vermont. Our assumption is that the manufacturers do not make most of their sales within Vermont. Rather, they sell to wholesalers or large retail chains outside Vermont, and those purchasers then come to Vermont and resell. Thus, the transactions regulated would be primarily transactions occurring outside of Vermont.

B. Analysis

The law is clear: an attempt to regulate prices of transactions occurring outside the state would violate the Commerce Clause. States may not regulate commerce occurring beyond their borders; laws that attempt to do so are extraterritorial and will be struck down as per se invalid. See Part One: I.B.1.

Because the Commerce Clause implications of such a proposal are clear, we do not address other constitutional problems that might arise with this proposal.

II. REGULATION OF WHOLESALE OR RETAIL TRANSACTIONS WHERE THE SALE TAKES PLACE WITHIN VERMONT

A. Features

The legislation would subject to a price cap or a specific price one or more in-state transactions involving the particular drug.

This proposal may also incorporate the Federal Supply Schedule or other price schedule as the basis for establishing the regulated in-state prices.

The proposal also might mandate the disclosure of price information.

B. Analysis

1. Commerce Clause

A court is likely to conclude that Vermont has jurisdiction under the Commerce Clause to regulate in-state transactions. As long as the price regulation treats out-of-state competitors and in-state competitors equally, and all competitors have equal access to other buyers and sellers in the state, state regulation of in-state prescription drug transactions will likely be analyzed under the balancing test rather than the "virtually per se invalid" test. See Part One: I.B.2.

The different outcomes in Ferndale and Cotto Waxo, discussed in Part One: I.B.2, underscore the difficulty in predicting how a court may apply the balancing test to prescription drug price regulation. In Ferndale, the court upheld Ohio's license requirement for out-of-state pharmaceutical wholesalers, finding the state's interest legitimate and little burden on interstate commerce. On the other hand, in Cotto Waxo, the court held that a trial was necessary to determine the adequacy of the state's interest, even though it found that the law minimally burdened interstate commerce; the court determined the statute simply may not be reasonably tailored to fulfill the state's interest.

Furthermore, although Ferndale involved pharmaceutical regulation, it provides little if any guidance for how a court would deal with price regulation of in-state pharmaceutical transactions. The burden posed in that case -- a $100 license fee and 2-page registration form -- was de minimus relative to the potential burden of price regulation. How a court may characterize the burdens and benefits of drug price regulation is difficult to predict. As a result, given the lack of precedent for state price regulation outside of the public utility context, we cannot predict the result of an application of the Commerce Clause balancing test to price regulation. However, we see no per se problem with such regulation.

Should the pricing regulation incorporate the FSS as a pricing benchmark, the potential problems identified in Part One: I.E.2, would apply to make the regulation vulnerable to a Commerce Clause challenge.

2. Supremacy Clause

Preemption problems could arise under this proposal if the FSS is used as a pricing benchmark, see Part One: II.C.4.a, and, depending on its details, potential ERISA problems could arise, see Part One: II.C.1.

3. Other Issues

This proposal would potentially raise the Contract Clause issues identified in Part One: III.B and III.C, the Takings Clause issues raised in Part One: IV.D and the Due Process concerns discussed in Part One: V.C.

III. STATE AS BUYER AND RESELLER OF PHARMACEUTICALS

A. Features

This proposal involves the state forming an entity which takes title to pharmaceuticals through direct purchases from manufacturers or other wholesalers. (In discussions, this proposal has been referred to as the "state as possessor" model.) Various formulations are possible. For example, the state may enter the market at the retail or the wholesale level. Furthermore, regardless of where it enters the market, the state may choose to enter through the use of a contract with a private party.

This proposal may or may not include restrictions on other businesses from competing with the state entity. On the one hand, the proposal may involve the state competing on even terms with other wholesalers or retailers; on the other hand, it may involve making the state entity the exclusive wholesaler through which all drugs in the state must pass. The latter scenario involves requiring all pharmaceuticals being sold in the state to pass through the state wholesaler. Under either of these two scenarios the state might wish to contract with a private party to serve the state entity. These two alternative scenarios are discussed separately in the analysis.

This proposal may also incorporate the Federal Supply Schedule or other price schedule as a benchmark for the purpose of establishing prices upon which the state entity would purchase pharmaceuticals.

Finally, the proposal might mandate the disclosure of price information.

B. Analysis

1. Commerce Clause

a. Unlimited Competitor Entry Into the Market

Vermont is free to participate in the market for pharmaceuticals, as retailer or wholesaler in the same way as any private business. The scenario discussed here assumes that the state forms a retail or wholesale entity as a market participant, but does not also regulate the market.

Under this scenario, the market participant doctrine should shield the entity from application of the Commerce Clause. See Part One: I.D. Like the state-owned cement plant in Reeves, as a retailer or wholesaler the state entity could favor in-state buyers or sellers over out-of-state businesses, much as a private entity may decide with whom to transact business (as long as it does not violate any other generally applicable laws). Moreover, the state would be free to contract with private entities to act as or serve the state entity.

Furthermore, it appears that the state could subsidize its retailer or wholesaler, so long as the subsidies were not funded by market competitors.

Finally, a state competitor left unprotected from competition would be free to use any price schedule, including the FSS. As a market participant, the state is acting like a private party, telling prospective sellers what prices the state is willing to pay. The state is not acting as a regulator when it states these prices, and therefore the Commerce Clause would not restrict its actions.

b. State as Exclusive Competitor in the Market

This alternative makes the state the sole first purchaser of drugs in the state. Conversely, the proposal excludes all competitors from the service of making the first purchase and reselling.

Challengers to this statute would have a strong argument that this alternative involves two distinct government actions:

1. the creation of the market participant, whose proprietary actions are immune from invalidation under the Commerce Clause, even if the entity buys or sells in ways favoring in-state economic interests (see above); and

2. the creation of a scheme of economic regulation, which excludes competitors and whereby an in-state entity (the state wholesaler or retailer) benefits to the detriment of out-of-state economic interests.

See New Energy Co. of Indiana v. Limbach, 486 U.S. 269, 277 (1988)(market participant doctrine "differentiates between a State's acting in its distinctive governmental capacity, and a State's acting in the more general capacity of a market participant."). See Part One: I.D.2.

Thus, as described in Part One: I.D.2, see in particular discussion of Atlantic Coast, 48 F.3d 701 (3rd. Cir. 1995), the "market participant" exception to the negative Commerce Clause may not protect aspects of Vermont legislation that may be deemed "regulatory." A requirement that all sales take place within the state, or one giving a single entity exclusive rights, is likely to be deemed regulatory. So labeled, it would be vulnerable to invalidation upon application of the rigorous scrutiny standard of Commerce Clause review. A court may analogize such legislation to Carbone, where the Supreme Court invalidated a town ordinance requiring that all waste generated in the town to pass through a local processing facility.

Although discrimination against interstate commerce in favor of local business or investment is generally held to be per se invalid, Vermont could still contend that pharmaceutical pricing laws fall within a narrow class of cases in which the state can demonstrate, under rigorous scrutiny, that it has no other means to advance a legitimate local interest. See Maine v. Taylor, 477 U.S. 131 (1986) (upholding Maine's ban on the import of baitfish because Maine had no other way to prevent the spread of disease to its native fish species). This would be a difficult hurdle, for the reasons set forth in Part One: I.A.2.

Should this alternative include the use of the FSS as a pricing benchmark, the potential problems identified in Part One: I.E.2 would apply as well.

2. Supremacy Clause

Under the regulated entry version of this proposal, preemption problems could arise if the FSS is used as a pricing benchmark, see Part One: II.C.4.a, and, depending on its details, potential ERISA problems could arise, see Part One: II.C.1.

In addition, under either the restricted entry version or the pure market participant version of this proposal, the state entity would be barred by federal law from buying drugs in Canada and reselling them in Vermont. See Part One: II.C.2.

3. Other Issues

The unrestricted entry version of this proposal would present no Contract Clause, Takings Clause, or Due Process Clause concerns.

The restricted market entry version would potentially raise the Contract Clause issues identified in Part One: III.B and III.C, the Takings Clause issues raised in Part One: IV.D and the Due Process concerns discussed in Part One: V.C.

IV. STATE AS PROGRAM ADMINISTRATOR OF DRUG DISCOUNT PLAN

A. Features

This proposal involves the creation of a state program to assist citizens in paying their prescription drug bills. It has been referred to in our discussions as the "state as payor" proposal.

The state would establish a price at which it is willing to reimburse pharmacies for selling at lower cost. The pharmacy would periodically bill the state for selling at discounted prices. The state would only reimburse pharmacies for drugs produced by manufacturers that have entered into an agreement with the state providing for manufacturer rebates for drugs sold through the program.

This proposal, like the previous one, may include regulatory aspects. Regulatory aspects may include, for example:

- requiring all Vermont citizens to purchase pharmaceuticals through the program for either (a) all prescription drugs or (b) only certain prescription drugs;
- requiring all retail sellers to participate in the program;
- requiring all retail sellers to sell at a discounted price whether or not they participate;
- prohibiting retail sellers who voluntarily participate from selling prescription drugs outside the program (i.e., pharmacy is all in or all out);
- requiring all manufacturers to participate in the program; and/or
- requiring manufacturers to participate for all their products or none of their products.

This proposal may also incorporate the Federal Supply Schedule or other price schedule as a benchmark for the purpose of establishing prices upon which the state entity would purchase pharmaceuticals.

Finally, this proposal might mandate the disclosure of price information.

B. Analysis

1. Commerce Clause

Absent any regulatory mandates, the manufacturers and the state's residents would be participating on a voluntary basis. Consequently, this proposal's Commerce Clause implications would resemble the market participant described in the "State as Buyer and Reseller of Pharmaceuticals" section above. See Part Two: II: III.B.1.a, and Part One: I.D. The state would be acting as a market participant, using its money to lower drug costs for its citizens, and telling prospective sellers what they can do to make their products attractive.

The picture changes if the program includes mandatory components. If the program required (a) all manufacturers to participate in the program, (b) all retail outlets to participate, or (c) all Vermont buyers to purchase their prescription drugs through the plan, the program would share similarities with the version of the "State as Buyer and Reseller of Pharmaceuticals" that restricts the entry of competitors into the market, and similar Commerce Clause issues arise. (This version will be called the regulatory version.) The Commerce Clause problems are noted above in Part Two: III.B.1.b.

Should the restrictive version of this alternative include the use of the FSS as a pricing benchmark, the concerns raised in Part One: I.E.2 would apply.

To the extent that buyers and sellers may decide whether or not to participate in the program but are otherwise impeded from freely transacting outside the program, those impediments would likely be analyzed under the balancing test described in Parts One I.A.3 and I.B.2. The burdens on interstate commerce would be weighed against the benefits of the program and the extent to which nonburdensome alternatives may be available. The outcome of such an analysis is difficult to predict.

Finally, a voluntary program would be free to use any price schedule, including the FSS, since the transactions would not be the product of a regulatory mandate.

2. Supremacy Clause

Under the regulated version of this proposal, preemption problems could arise if the FSS is used as a pricing benchmark, see Part One: II.C.4.a, and, depending on its details, potential ERISA problems could arise, see Part II.C1.

In addition, under either the restricted entry version or the pure market participant version of this proposal, the state program would be barred from buying drugs in Canada and reselling them in Vermont. See Part One: II.C.2.

3. Other Issues

The voluntary version of this proposal would present no Contract Clause, Takings Clause, or Due Process Clause concerns.

The regulatory version would potentially raise the Contract Clause issues identified in Part One: III.B and III.C, the Takings Clause issues raised in Part One: IV.D and the Due Process concerns discussed in Part One: V.C.

V. REQUIREMENT OF "BEST PRICE" OR NONDISCRIMINATION

A. Features

Legislation under this proposal would require that all sellers of prescription drugs offer to every purchaser the same prices and discounts provided by the seller to the most favored purchaser. Thus, every buyer would be entitled to buy at the best price the seller offered. The law may allow sellers to provide discounts for volume purchasers, but all purchasers of similar volume would be entitled to the lowest price accorded to any of them. The law therefore would bar price discrimination among similarly situated purchasers.

This proposal also might mandate the disclosure of price information.

B. Analysis

1. Commerce Clause

This proposal must be limited to the best in-state price. The Supreme Court has made it clear that a state may not require sellers to sell at the seller's best price in another state. See Part One: I.E.1.

If limited to the best in-state sales, there is clear precedent upholding such a proposal. See K-S Pharmacies v. American Home Corp., 962 F.2d 728, 730 (7th Cir. 1992)(upholding Wisconsin's nondiscrimination pharmaceutical pricing statute), discussed in Part One: I.E.1.

2. Supremacy Clause

The Supreme Court has upheld state laws that operate similarly to nondiscrimination statutes against assertions that they violate federal antitrust law. See Part One: II.D.4.

3. Other Issues

Unless applied retroactively, a nondiscrimination statute is unlikely to raise any Contract, Takings, or Due Process Clause problems.

VI. Conditioning Manufacturer’s License on Making Sales Within the State

Although pharmaceutical manufacturers do not make many direct sales in Vermont, they do engage in certain other activities. These activities include promoting the purchase of their pharmaceuticals through visits to potential buyers or prescribing entities. One proposal seeks to use these activities as a basis for in-state price regulation. Specifically, the proposal would (a) require manufacturers to obtain a license to engage in these activities, and (b) condition this license on the manufacturer agreeing that any sales it made to an in-state purchaser take place within the state. Having thus required a Vermont situs for these sales, the legislation then would subject the sales to in-state price regulation.

Although the state could require licenses for the in-state promotional activities consistent with the Due Process Clause and the Commerce Clause, we do not think the license condition requiring sales to be in-state would pass constitutional muster. A licensing requirement, based on activities inside the state, cannot be used to regulate activities that occur outside the state. Such regulation would occur when the state required, as a condition of a license, that transactions normally undertaken by the licensee outside the state be rearranged to occur inside the state.

Such a requirement would discriminate against interstate commerce directly. By requiring those who sell to in-state residents to conduct those transactions within the state, the law explicitly favors its own markets over markets in other states. This discrimination against commerce taking place outside the state, in favor of commerce within the state, is barred by the Commerce Clause. <u>See</u> the discussion of <u>Dean Milk Co. v. Madison</u>, 340 U.S. 349 (1951) (invalidating city ordinance requiring all milk sold in the city to be pasteurized within five miles of the city lines); <u>Minnesota v. Barber</u>, 136 U.S. 313 (1890) (striking down Minnesota requirement that any meat sold within the state, whether originating within or without the State, be examined by an inspector within the State); <u>Toomer v. Witsell</u>, 334 U.S. 385 (1948) (invalidating South Carolina law requiring shrimp fishermen to unload, pack, and stamp their catch before shipping it to another State), in Part One, I.C.2.b. above.

Moreover, that the licensing condition would benefit the state by facilitating in-state price regulation does not alter its discriminatory character. <u>Toomer</u>, <u>supra</u>, at 334 U.S. at 406 ("The importance of having commerce between the forty-eight States flow unimpeded by local barriers persuades us that State restrictions inimical to the commerce clause should not be approved simply because they facilitate in some measure enforcement of a valid tax."). To see this result more clearly, suppose that in addition to Vermont's action, the state in which the manufacturer was located, hoping to increase its tax base, enacted legislation requiring that any sales made by the manufacturer take place within that state. The burden on commerce would be clear, because the manufacturer could not comply with both states' laws. <u>Cf.</u> <u>Toomer</u>, <u>supra</u>, 334 U.S. at 403-04 ("the necessary tendency of the statute is to impose an artificial rigidity on the economic pattern of the industry").