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OPINION	:	No. 91-305
of	:	
	:	<u>MARCH 3, 1992</u>
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THE HONORABLE TRICIA HUNTER, MEMBER OF THE CALIFORNIA ASSEMBLY, has requested an opinion on the following questions:

1. Do California laws governing pharmacies apply to out-of-state mail order pharmacies filling prescriptions and mailing them to people in California?
2. Is California's current regulation of out-of-state mail order pharmacies consistent with the commerce clause of the United States Constitution?
3. Under California law, may a generic type drug listed on the negative drug formulary established by the Director of Health Services be substituted for a brand name drug by an out-of-state pharmacy when filling prescriptions and mailing them to people in California?

CONCLUSIONS

1. California laws governing pharmacies apply in limited circumstances to out-of-state mail order pharmacies filling prescriptions and mailing them to people in California.
2. California's current regulation of out-of-state mail order pharmacies is consistent with the commerce clause of the United States Constitution.
3. Under California law, a generic type drug listed on the negative drug formulary established by the Director of Health Services may be substituted for a brand name drug by an out-of-state pharmacy when filling prescriptions and mailing them to people in California, if the pharmacy is registered as a nonresident pharmacy.

## ANALYSIS

### 1. California's Pharmacy Laws

The first question presented for analysis is whether the laws governing pharmacies within California are applicable to out-of-state pharmacies filling prescriptions and mailing them to people in California. We conclude that they are in limited circumstances.

The laws governing pharmacies dispensing drugs in California are found generally in chapter 9 of division 2 of the Business and Professions Code (§ 4000 et seq.).<sup>1</sup> Additional provisions having specific application to pharmacists appear in the Health and Safety Code as part of the Uniform Controlled Substances Act (Health & Saf. Code, § 11000 et seq.) and the Sherman Food, Drug and Cosmetic Law (Health & Saf. Code, § 26000 et seq.).

A person within the state who sells or dispenses dangerous drugs or devices must be registered as a pharmacist with the State Board of Pharmacy ("Board"). (§§ 4050, 4085.) Section 4084.6 prohibits an out-of-state pharmacy from doing business in California unless it obtains an out-of-state drug distributor's license or registers as a nonresident pharmacy.<sup>2</sup> It states in part:

"No out-of-state manufacturer, wholesaler, or pharmacy doing business in this state who has not obtained a certificate, license, permit, registration, or exemption from the board and who sells or distributes drugs in this state through any person or media other than a wholesaler who has obtained a certificate, license, permit, registration, or exemption pursuant to the provisions of this chapter or through a selling or distribution outlet which is licensed as a wholesaler pursuant to the provisions of this chapter, shall conduct the business of selling or distributing drugs in this state without obtaining an out-of-state drug distributor's license from the board or registering as a nonresident pharmacy.

" . . . . .

"The board may deny, revoke, or suspend such out-of-state distributor's license for any violation of this chapter or for any violation of Division 21 (commencing with Section 26000) of the Health and Safety Code . . . ."

Accordingly, under the terms of section 4084.6, if an out-of-state pharmacy is licensed as an out-of-state drug distributor, it must comply with "this chapter" (§§ 4000-4480) and "Division 21" (Health and Saf. Code, §§ 26000-26851.1).

If a pharmacy registers as a nonresident pharmacy, it is required to comply with the limited set of regulations specified in section 4350.6. Section 4350.6 states in part:

"The board may deny, revoke, or suspend a nonresident pharmacy registration for failure to comply with any requirement of Section 4050.1 or 4383 or for any failure to comply with Section 11164 of the Health and Safety Code."

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<sup>1</sup>All references herein to the Business and Professions Code are by section number only.

<sup>2</sup>Registration as a nonresident pharmacy is available "only to a nonresident pharmacy which only ships, mails, or delivers controlled substances and dangerous drugs and devices into this state pursuant to a prescription." (§ 4050.1, subd. (d).)

Section 4050.1 requires a nonresident pharmacy to (1) disclose to the Board its officers and pharmacists, (2) comply with all laws of the state in which it is a resident, (3) maintain its records so that they are readily retrievable concerning controlled substances and dangerous drugs dispensed to patients in California, and (4) provide a toll-free telephone service for patients in California, among other requirements.

Besides the conditions for doing business in California specified in section 4050.1, a nonresident pharmacy must comply with section 4383 concerning advertising its services within California and Health and Safety Code section 11164 regarding filling prescriptions for controlled substances. As set forth in section 4350.6, these are the only California statutes with which a nonresident pharmacy must comply in order to retain its California registration.

In answer to the first question, therefore, we conclude that California laws governing pharmacies apply in limited circumstances to an out-of-state mail order pharmacy filling prescriptions and mailing them to people in California. If it is licensed as an out-of-state drug distributor, it must comply with sections 4000-4480 and Health and Safety Code sections 26000 - 26851.1. (§4084.6.) If it is registered as a nonresident pharmacy, it must comply with sections 4050.1, 4383, and Health and Safety Code section 11164. (§4350.6)

## 2. The Commerce Clause

The second question presented for resolution concerns whether California's current regulation of out-of-state mail order pharmacies is consistent with the commerce clause of the United States Constitution.

The commerce clause of the United States Constitution provides in pertinent part: "The Congress shall have power . . . to regulate commerce . . . among the several states . . . ." In addition to being a direct grant of power to the federal government, the commerce clause stands as a limitation on the exercise of state power in matters affecting the movement of persons and things across state lines. The states may not substantially impede the free flow of commerce from state to state, but the lawful exercise of their police and taxing powers in matters of local concern may include limited impacts on interstate commerce in areas not already preempted by congressional action. (*Southern Pacific Co. v. Arizona* (1945) 325 U.S. 761, 766-767.)

In determining whether a state-created impact on interstate commerce falls within permissible bounds, the United States Supreme Court has employed the following balancing test:

"Where the statute 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 on interstate activities." (*Pike v. Bruce Church, Inc.* (1970) 397 U.S. 137, 142.)<sup>3</sup>

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<sup>3</sup>These principles were recently restated by the court in *Brown-Forman Distillers Corp. v. New York State Liquor Authority* (1986) 476 U.S. 573, 578:

"This Court has adopted what amounts to a two-tiered approach to analyzing

The foregoing approach is generally applied to cases in which the state regulation may be deemed nondiscriminatory, that is, where the state does not seek to gain a competitive advantage, shift the burdensome aspects of commerce to another state, or otherwise seek to isolate itself economically. Where, however, a discriminatory intent is evident, the court will apply a virtual "per se" rule of invalidity. (See *Lewis v. BT Investment Mgrs.* (1980) 447 U.S. 27, 38-42; *City of Philadelphia v. New Jersey* (1978) 437 U.S. 617, 623-624; *New England Power Co. v. New Hampshire* (1982) 455 U.S. 331, 339.)

A local purpose which has traditionally been favored by the court is one promoting the health and safety of a state's inhabitants. The court has, from the time of its earliest decisions, acknowledged pursuit of that interest as being at the heart of a state's responsibilities. (*Wilson v. Black Bird Creek Marsh Co.* (1829) 27 U.S. (2 Pet.) 245, 250; *Gibbons v. Ogden* (1824) 22 U.S. (9 Wheat) 1, 205.) In the modern constellation of state interests, health and safety continues to loom large. Relative to economic interests, for instance, protecting health and safety has enjoyed a clearly preferred status:

"This distinction between the power of the State to shelter its people from menaces to their health or safety and from fraud, even when those dangers emanate from interstate commerce, and its lack of power to retard, burden or constrict the flow of such commerce for their economic advantage, is one deeply rooted in both our history and our law . . . . This Court consistently has rebuffed attempts of states to advance their own commercial interest by curtailing the movement of articles of commerce . . . while generally supporting their right to impose even burdensome regulations in the interest of local health and safety." (*H.P. Hood & Sons v. DuMond* (1949) 336 U.S. 525, 533, 535.)

Further evidence of the weight given to a state's health and safety concerns can be found in cases which have allowed states to burden interstate commerce in the furtherance of clean air and water quality. (*Huron Portland Cement Co. v. City of Detroit* (1960) 362 U.S. 440, 442 ["Legislation designed to free from pollution the very air that people breathe clearly falls within the exercise of the most traditional concept of the police power"]; *Sporhase v. Nebraska ex rel. Douglas* (1982) 458 U.S. 941, 956 [". . . a State's power to regulate the use of water . . . for the purpose of protecting the health of its citizens -- and not simply the health of its economy -- is at the core of its police power"].)

While a state's interest in protecting the health and safety of its citizens can carry great weight, a regulation adopted pursuant to that interest will be scrutinized to determine whether, although the ends are legitimate, the state has chosen as its means the curtailment of competition by out-of-state parties or has a secondary purpose of effecting such curtailment. (See *H.P. Hood &*

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state economic regulation under the Commerce Clause. When a state statute directly regulates or discriminates against interstate commerce, or when its effect is to favor in-state economic interests over out-of-state interests, we have generally struck down the statute without further inquiry. When, however, a statute has only indirect effects on interstate commerce and regulates evenhandedly, we have examined whether the State's interest is legitimate and whether the burden on interstate commerce clearly exceeds the local benefits. We have also recognized that there is no clear line separating the category of state regulations that is virtually *per se* invalid under the Commerce Clause, and the category subject to the *Pike v. Bruce Church* balancing approach. In either situation the critical consideration is the overall effect of the statute on both local and interstate activity. . . ."

*Sons v. DuMond*, *supra*, 336 U.S. at 538; *Baldwin v. G.A.F. Seelig, Inc.* (1935) 294 U.S. 511, 523.) In *Dean Milk v. City of Madison* (1951) 340 U.S. 349, a state's interest in healthful milk did not save the regulation in question. The court viewed the regulation as containing elements of economic protectionism and determined that a less burdensome alternative could have been employed.

Where the avowed purpose of the regulation is not illusory or suspect, the court will, even in the health and safety context, proceed with a balancing test. "Regulations designed for that salutary purpose nevertheless may further the purpose so marginally, and interfere with commerce so substantially, as to be invalid under the Commerce Clause." (*Kassel v. Consolidated Freightways Corp.* (1981) 450 U.S. 662, 670.)

Here, the outcome of the commerce clause balancing test supports California's current regulation of out-of-state mail order pharmacies for purposes of health and safety. It is evident that the state has considerable latitude for regulation in this area. California's laws do not discriminate against interstate commerce or discriminate in favor of in-state economic interests so as to offend the commerce clause. The burden placed on interstate commerce is clearly minimal in relation to the legitimate state purpose of protecting the health and welfare of California residents.

In answer to the second question, therefore, we conclude that California's current regulation of out-of-state mail order pharmacies is consistent with the commerce clause of the United States Constitution.

### 3. The Negative Drug Formulary

The third question concerns California's "negative drug formulary." Section 4047.6 provides generally that:

"A pharmacist filling a prescription order for a drug product prescribed by its trade or brand name may select another drug product with the same active chemical ingredients of the same strength, quantity and dosage form, and of the same generic drug type . . . ."

Thus, with certain exceptions and qualifications, section 4047.6 allows a pharmacist to substitute a generic drug for a brand name drug when filling a prescription.

One exception applies when the generic drug type or drug product has been listed on the "negative drug formulary" by the Director of Health Services. Section 4047.7 states:

"(a) The Director of Health Services shall establish by regulation a formulary of generic drug types and drug products which the Director of Health Services determines demonstrate clinically significant biological or therapeutic inequivalence and which, if substituted under Section 4047.6, would pose a threat to the health and safety of patients receiving prescription medication.

".....

"(d) Upon adoption of the formulary, and upon each addition, deletion or modification to the formulary, the Director of Health Services shall mail a copy to each pharmacist licensed by the State Board of Pharmacy and to each physician and surgeon licensed to practice in the state by the Medical Board of California and each person licensed by the Osteopathic Medical Board of California. No pharmacist

shall dispense a generically equivalent drug product pursuant to Section 4047.6 if the drug product and its generic drug type is included in the formulary."

If a drug is listed by the Director of Health Services on the negative drug formulary,<sup>4</sup> a pharmacist may not substitute it for a brand name drug as otherwise authorized under section 4047.6.

Compliance with section 4047.7 is required of all pharmacies in California and any pharmacy licensed as an out-of-state drug distributor pursuant to section 4084.6. As previously noted, however, a pharmacy registered as a nonresident pharmacy under section 4050.1 must comply only with sections 4050.1 and 4383 and Health and Safety Code section 11164 in order to maintain its registration, and hence its ability to do business in California. (§ 4350.6.)

In answer to the third question, therefore, we conclude that under California law a generic type drug listed on the negative drug formulary established by the Director of Health Services may be substituted for a brand name drug by an out-of-state pharmacy when filling prescriptions and mailing them to people in California, if the pharmacy is registered as a nonresident pharmacy.

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<sup>4</sup>We are informed that no drug is currently listed on the negative drug formulary.