

Charlie Adams

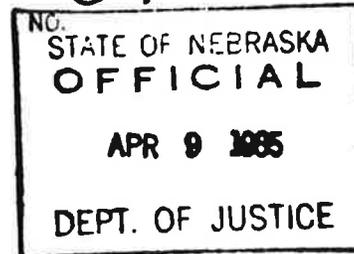
DEPARTMENT OF JUSTICE

STATE OF NEBRASKA

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Attorney General
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Deputy Attorney General

April 4, 1985



Senator Don Wesely
Nebraska State Legislature
1402 State Capitol
Lincoln, NE 68509

Dear Senator Wesely:

This letter is in response to your earlier correspondence in which you requested our opinion as to the constitutionality of LB 578. Specifically, you asked whether LB 578 violates any state or federal constitutional provisions including the Commerce Clause of the United States Constitution. We have reviewed the bill in question along with various relevant legal authorities. As is discussed below, we have concluded that LB 578 is of suspect constitutional validity.

LB 578 would require pharmacies operating outside the State of Nebraska which mail dispensed prescription drugs into the state to obtain a pharmacy license issued by the Nebraska Department of Health. Such pharmacies would also be required to dispense prescription drugs in Nebraska in compliance with Nebraska law governing the practice of pharmacy. The text of the bill, in its entirety, is as follows:

Any pharmacy operating outside the State of Nebraska which ships, mails, or delivers in any manner a dispensed prescription drug into the State of Nebraska shall hold a pharmacy license issued by the Department of Health, and that part of such pharmacy operation which dispenses prescriptions to Nebraska residents shall comply with Nebraska law, rules, and regulations governing the practice of pharmacy. The Department of Health, upon recommendation of the Board of Examiners in Pharmacy, shall adopt and promulgate rules and regulations,

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including provisions for enforcement, necessary to carry out this section.

The constitutionality of a state's attempt to license or otherwise regulate out-of-state pharmacies which mail prescription drugs into the state has been considered previously by various authorities with differing results. For example, the Attorneys General of Wisconsin and California have indicated that such regulation is constitutionally permissible under the Commerce Clause of the United States Constitution. In contrast, the Attorney General of Ohio has indicated that such regulation is unconstitutional. Given these conflicting authorities, we must proceed with our own independent analysis of your question.

LB 578, by its express language, applies to pharmacies outside the State of Nebraska which ship or otherwise deliver dispensed prescription drugs into the state. Interstate commerce is commerce between the states as opposed to commerce wholly within a state. Ware & Leland v. Mobile County, 209 U.S. 405 (1908). Consequently, LB 578 involves an attempt by the State of Nebraska to regulate a form of interstate commerce. There is no question but that the state can subject wholly intrastate commerce to regulation under its police power. However, an attempt to regulate interstate commerce must be tested under the Commerce Clause of the United States Constitution.

The Commerce Clause gives the United States Congress the authority to regulate commerce with foreign nations, among the states, and with the Indian tribes. This authority includes full plenary power to regulate interstate commerce. In Re Rules and Regulations Nos. 31 and 32, 193 Neb. 59, 225 N.W.2d 401 (1975). Accordingly, federal statutes passed by Congress pursuant to its powers concerning interstate commerce are capable of preempting any state legislation or regulation of the same subject. Id. Therefore, we must first inquire in the present instance as to whether any federal legislation has preempted the state regulation contemplated by LB 578.

In 1970, Congress passed the Drug Abuse Prevention and Control Act, 21 U.S.C. §§801 et seq. The various provisions of that Act comprehensively regulate the distribution and dispensing of controlled substances in interstate commerce throughout the United States. For example, provisions of the Act deal with registration requirements, labeling and packaging of drugs, prescription of controlled substances, and records and reporting requirements. A review of the substantive provisions of that Act would lead to the conclusion that Congress did intend to preempt

regulation in this area of interstate commerce. However, §903 of the Act, 21 U.S.C. §903, states:

No provision of this subchapter shall be construed as indicating an intent on the part of Congress to occupy the field in which that provision operates, including criminal penalties, to the exclusion of any state law on the subject matter which would otherwise be within the authority of the state, unless there is a positive conflict between that provision of this subchapter and that state law so that the two cannot consistently stand together.

This statutory language indicates that Congress did not intend to preempt state regulation of interstate commerce involving controlled substances so long as any state regulation does not directly conflict with the Act itself. Thus, LB 578 is not preempted so long as it does not directly conflict with the federal Act. See, Ranger Division, Ryder Truck Lines, Inc. v. Bayne, 214 Neb. 251, 333 N.W.2d 891 (1983). LB 578 would subject out-of-state pharmacies which mail prescription drugs into Nebraska to the various Nebraska statutes and regulations dealing with the licensing and operation of pharmacies. Our review of those statutes indicates that they largely parallel the provisions of the federal Drug Abuse Prevention and Control Act. Consequently, we do not believe that the Nebraska statutes and the federal law are in direct conflict, and we do not believe that the federal legislation preempts the regulation contemplated by LB 578. We are aware of State v. Rasmussen, 213 N.W.2d 661 (Iowa 1973) in which the Supreme Court of Iowa indicated that parallel Iowa legislation dealing with the registration of nonresident prescribing physicians would, in practical effect, negate the operation of the federal drug act. However, we do not find the Iowa case conclusive in the context of the question presently before us.

The purpose of the Commerce Clause in the United States Constitution is to create an area of trade among the states free from interference by the various states. A & P Tea Company v. Cottrell, 424 U.S. 366 (1976). Therefore, separate and apart from the preemption question, the Commerce Clause acts as a limitation upon the powers of the states even when Congress has not passed federal legislation in a particular area. Id. However, not every exercise of state power is invalid merely because it affects interstate commerce in some way. Id.; Ranger Division, Ryder Truck Lines v. Bayne, supra. The United States Supreme Court has established the following criteria for

determining the validity of state statutes affecting interstate commerce:

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. 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, 397 U.S. 137, 142 (1970) (citations omitted) (emphasis added).

It therefore becomes necessary to analyze LB 578 under the criteria established in Pike v. Bruce Church.

At the outset, it is apparent that the regulation contemplated by LB 578 serves a legitimate and important local public interest. That regulation directly involves protection of the public health, and is therefore within the most traditional concept of the state's police power. Head v. Board of Examiners, 324 U.S. 424 (1963). The state clearly has a strong and legitimate local interest in regulating the manner in which drugs are dispensed to its citizens.

On its face, LB 578 also appears to regulate evenhandedly and in a fashion which does not discriminate against interstate commerce. LB 578 provides that out of state pharmacies dispensing controlled substances within the state must hold a pharmacy license issued by the Department of Health and must comply with Nebraska law governing the practice of pharmacy. Obviously, Nebraska pharmacies in the state operating wholly within intrastate commerce must comply with exactly the same provisions.

We have more difficulty with that portion of the Bruce Church criteria which states that the effects of the state regulation on interstate commerce must only be incidental. LB 578 would submit a pharmacy located in another state to Nebraska law concerning licensing and the practice of pharmacy. If that out-of-state pharmacy dispenses drugs through the mail to customers in a number of states, it would seem to us that having to meet the licensing requirement of each particular state would

impose a substantial burden upon the pharmacy's ability to engage in interstate commerce. In such an instance, the pharmacy involved would be subject to multiple licensing procedures including duplicative registrations, records requirements, and labeling requirements.

Finally, and most importantly in terms of the present question, the Bruce Church criteria include an evaluation of the local interest involved and an evaluation of whether that interest could be promoted as well in some manner with a lesser impact on interstate commerce. Later cases have interpreted this criterion to encompass a consideration of the consequences to the state if its proposed regulatory action were disallowed, or a consideration of whether a substantial regulatory equivalent is available to the state. A & P Tea Company v. Cottrell, supra; Dixie Dairy Company v City of Chicago, 538 F.2d 1303 (7th Cir. 1976).

Our research in the present instance indicates that the federal Drug Abuse Prevention and Control Act of 1970 extensively regulates pharmacies which dispense controlled substances within the United States along with the various practices involved in dispensing those controlled substances. For example, federal regulations require persons dispensing controlled substances to register with the United States Department of Justice. 21 C.F.R. §1301.21. Federal regulations establish labeling and packaging requirements for controlled substances. 21 C.F.R. §1302.03. Federal regulations establish various requirements for the maintenance of records involving dispensation of drugs and inventories of controlled substances. 21 C.F.R. §1304.24. Federal regulations provide that prescriptions for controlled substances may only be filled by a professional pharmacist. 21 C.F.R. §1306.06. Our review of the various Nebraska statutes dealing with the practice of pharmacy which would apply to pharmacies located out of the State of Nebraska under the provisions of LB 578 indicates that those pharmacy provisions substantially duplicate the provisions of the federal act. Consequently, even though the state admittedly has an important public interest in regulating the dispensing of controlled substances, it seems to us that the existing federal statutes are substantially equivalent to the Nebraska statutes. In addition, the existing federal statutes protect the state's interests so that the consequences to the state are minimal if its attempt to regulate out-of-state pharmacies under the provisions of LB 578 is disallowed. Given the federal statutory framework, the state's regulatory interest under LB 578 is simply not great enough to justify the burden which that bill would place upon interstate commerce. Therefore, LB 578 is of suspect

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constitutional validity under the criteria established in Pike v. Bruce Church, supra.

We are aware of Pharmaceutical Manufacturers Association v. New Mexico Board of Pharmacy, 86 N.M. 471, 525 P.2d 931 (1974), where the Court of Appeals of New Mexico held that state pharmacy regulations requiring registration by out-of-state sellers and shippers of dangerous drugs were constitutional under the Commerce Clause. We would simply note that the burden on interstate commerce created by registration in that case was substantially less than the burden imposed by licensing under LB 578. We would also note, as discussed earlier, that the various authorities are in conflict on this issue.

One final matter remains. The United States Supreme Court has indicated that state attempts to regulate interstate commerce which may be considered as simple economic protectionism are virtually invalid per se. Philadelphia v. New Jersey, 417 U.S. 617 (1978). In the present instance, no such economic protectionism is apparent from the plain language of LB 578. However, if LB 578 could be considered as an attempt to protect pharmacies located within the State of Nebraska from competing pharmacies located out-of-state, then LB 578 would be a form of economic protectionism invalid under the United States Constitution.

In summary, we do not believe that LB 578 is preempted by the federal legislation controlling the flow of controlled substances within interstate commerce. However, while we feel that the state has legitimate and strong interest in regulating the process of dispensing drugs, we believe that the regulation envisioned by LB 578 is more than an incidental burden on interstate commerce, and that the state's interest in regulating the flow of controlled substances is adequately protected by the pertinent federal statutes. Consequently, it is our opinion that LB 578 is of suspect constitutional validity under the Commerce Clause of the United States Constitution.

Sincerely yours,

ROBERT M. SPIRE
Attorney General



A. Eugene Crump
Deputy Attorney General

AEC:bmh

cc: Patrick J. O'Donnell
Clerk of the Legislature