N.D.A.G. Letter to Koland (Feb. 26, 1987)

February 26, 1987

Honorable Dave Koland House of Representatives State Capitol Bismarck, ND 58505

Dear Representative Koland:

In a letter dated January 27, 1987, House Majority Leader Earl Strinden forwarded your request for an Attorney General's opinion on Senate Bill No. 2173. The request appears to raise the issue of whether the bill places an unreasonable burden on interstate commerce in violation of the United States Constitution by regulating out-of-state pharmacies and requiring them to register with the North Dakota Board of Pharmacy if they dispense and ship prescription drugs into the state.

The issue of whether a state may regulate the dispensing of drugs outside of its territorial boundaries has arisen in many states during the past several years; however, there is presently no case law directly on the issue. In addition, opinions by the Attorneys General of several states have reached different conclusions on whether such state laws unduly burden interstate commerce in violation of the Commerce Clause of the United States Constitution.

The Commerce Clause, U.S. Const. Art. I, §8, cl. 3, grants to Congress the power "[t]o regulate commerce . . . among the several states" In addition to authorizing Congress to regulate interstate commerce, the clause has also been interpreted to limit the power of the states to erect barriers that restrict interstate commerce. The states may, however, enact laws for the protection of public health, safety, or welfare under their police powers that do not conflict with federal legislation or unreasonably burden interstate commerce.

State police power regulations affecting interstate commerce will be found invalid if there has been federal preemption over the area of regulation. That is, if Congress has determined that a certain aspect of interstate commerce must be solely regulated by federal law because of a need for uniformity which supersedes the need for local regulation, the federal law would preempt local regulation of the same subject.

A state police power regulation may also be invalid under the Commerce Clause, even in the absence of superseding federal legislation, if the local law constitutes an unreasonable burden on interstate commerce. The test for determining whether a state law constitutes an unreasonable burden on interstate commerce was set forth by the United States Supreme Court in <u>Pike v. Bruce Church, Inc.</u>, 397 U.S. 137, 142 (1970), as follows.

Where the statute regulates even-handedly 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. Huron Portland Cement Co. v. City of Detroit, 362 U.S. 440, 443. 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.

In determining the constitutionality of a statute affecting interstate commerce courts will focus on the practical operation of the statute and its probable effects.

It cannot be disputed that a mail order pharmacy transaction in which a North Dakota resident sends a prescription to an out-of-state pharmacy and the out-of-state pharmacy dispenses and delivers the prescription back to the North Dakota resident through the mail constitutes interstate commerce. Senate Bill No. 2173 would clearly affect interstate commerce.

The bill also appears to be a legitimate exercise of the state's police powers because regulating the control of prescription drugs constitutes an important health, safety, or welfare regulation. The regulation of the practice of pharmacy has specifically been found to be a legitimate exercise of the police power by various state courts.

It is not as clear, however, whether Congress has preempted the power of the state to enact a police power regulation that affects interstate commerce in prescription drugs as does Senate Bill No. 2173. Congress has passed substantial legislation regulating the interstate flow of controlled substances including the Controlled Substances Act of 1970 and other laws. 21 U.S.C. § 903 provides, in part:

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 . . . unless there is a positive conflict between that provision of this subchapter and that state law so that the two cannot consistently stand together.

There is no controlling case law to assist us in determining whether Senate Bill No. 2173 would directly conflict with federal drug laws and, therefore, be preempted by them. The lowa Supreme Court in <u>State v. Rasmussen</u>, 213 N.W.2d 661 (lowa 1973), held that a state law prohibiting lowa pharmacists from filling prescriptions written by nonresident physicians not licensed by the state of lowa directly conflicted with federal drug laws regulating interstate commerce in drugs and was preempted by federal law. On the other hand, the Court of Appeals of New Mexico in <u>Pharmaceutical Manufacturers' Association v. New Mexico Board of Pharmacy</u>, 525 P.2d 931 (N.M. App. 1974), recognized the mutual federal and state interests in drug control and found no federal preemption of state

regulations requiring drug manufacturers, sellers, and shippers within the state to pay a \$100 annual fee.

Because of the lack of case law on the issue of federal preemption of state regulation of out-of-state pharmacies, it is difficult to definitely state whether or not a court would determine Senate Bill No. 2173 to be preempted by federal law. However, even in the absence of federal preemption, a court would still need to decide whether or not the law places an unreasonable burden on interstate commerce.

In determining the constitutionality of Senate Bill No. 2173, a court would need to determine whether the burden imposed on interstate commerce is excessive when balanced against the putative local benefits provided by the law. Testimony in support of Senate Bill No. 2173 before the Senate Industry, Business and Labor Committee suggests that the state would benefit by requiring all pharmacies dispensing prescriptions to North Dakota residents to register and comply with North Dakota's high pharmacy standards.

By requiring registration, the Board of Pharmacy would know who is shipping prescription drugs into the state, whereas it does not presently have that information. Other benefits would include requiring pharmacies to follow North Dakota laws and regulations such as maintaining patient profile record systems (N.D.C.C. § 43-15-31.1) and providing a patient consultation on an initial prescription (N.D.C.C. § 43-15-31.2). According to the testimony, there is a greater need for these specific protections, which are not provided in many states, in the case of mail order pharmacies where there is no face-to-face meeting between the patient and pharmacist. It was further asserted that the patient profile requirement can avoid inadvertent drug interaction problems and the patient consultation requirement helps to prevent improper use of medication by patients.

Senate Bill No. 2173 does affect interstate commerce through its pharmacy registration requirement, \$300 fee, the patient profile, initial consultation, and other requirements under state law. The bill, by itself, may not appear to constitute an unreasonable burden on interstate commerce. However, in determining the constitutionality of a state statute under the Commerce Clause, a court may look to the potential burden of multiple registration requirements, registration fees, and conflicting pharmacy laws of all 50 states in determining whether or not an unreasonable burden exists.

In order to rule on the constitutionality of Senate Bill No. 2173, a court will be required to conduct a very detailed factual analysis of the respective benefits and burdens to decide whether the law has only an incidental effect or places an unreasonable burden on interstate commerce. Because the issue in question has never been decided by any court and a complete factual analysis of the effects of the bill is not presently before us, an opinion on how a court would likely resolve the delicate balancing of interests would be quite speculative. Strong arguments can clearly be raised on both sides of the issue

In conclusion, although a different result is possible, Senate Bill No. 2173 does not appear to directly conflict with federal law and would not be preempted by it. It is my further opinion that Senate Bill No. 2173 is a legitimate police power regulation which protects the public health, safety, and welfare through the regulation of an important area of interest and could possibly withstand constitutional scrutiny under the Commerce Clause. However, it is possible that a court may find the bill to unduly burden interstate commerce because of the potential for multiple registration requirements, registration fees, and conflicting pharmacy laws of all 50 states. It is my further opinion that a constitutional challenge may occur if Senate Bill No. 2173 were enacted and actively enforced against out-of-state mail order pharmacies doing business in North Dakota.

Sincerely,

Nicholas J. Spaeth

dfm cc: Hon. Earl Strinden