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INTERNET LAW

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State E-Pharmacy Regulation

State regulation of Internet prescription transactions may violate Commerce Clause

The New York State Narcotic Bureau of Enforcement is investigating companies in New Jersey, Mississippi and elsewhere for facilitating Internet prescription medicine transactions. These facilitators include Web site owners, database providers and Internet service providers, none of which have New York offices, assets or residents. Any indictments or convictions resulting from such New York investigations may be barred by the Commerce Clause.

Acquiring medications via the Internet is not per se unlawful. By some estimates, nearly 30 percent of United States households purchased medicine online. Americans increasingly rely on the Internet to dispense and fill prescriptions. Consequently, states are

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seeking to enforce state Internet pharmacy regulations on nonresidents.

States and the federal government must balance the benefits and perils posed by Internet pharmacies. The regulation of Internet-related activities concerning medications, physicians and pharmacists is divided between state and federal authorities. Purely intrastate Internet activities are arguably the jurisdiction of a particular state. However, some state restrictions of Internet pharmacy transactions reach beyond state lines and, therefore, appear to violate the Commerce Clause, which acts as a limitation on state regulatory authority.

Historically, under Article X of the U.S. Constitution, states have the authority to regulate activities that affect the health, safety and welfare of their citizens. In 1889, state licensure systems that granted physicians the exclusive right to prescribe and pharmacists the exclusive right to dispense prescription medication were tested and found to be valid. In *Dent v. West Virginia*, 129 U.S. 114 (1889), the Supreme Court denied a due process challenge to a West Virginia medical practice act that required state licensure of physicians.

More than one-third of states have amended their licensure rules to manage Internet prescribing by supplementing existing telemedicine statutes and added new definitions of legally "safe" consulting relationships. However, states are diverging with respect to promoting

Internet prescribing. Several jurisdictions have amended their licensing laws to specifically include electronic diagnosis, while others states' amendments specifically require face to face diagnosis.

In addition to the divergence among states regarding the promotion of Internet prescription transactions, the extent of the revisions of licensure regulation concerning the use of the Internet also varies. Arizona's licensure update addresses both intrastate and interstate consultations. Montana's licensure update only addresses exchanges between physician and patient, without dealing with pharmacy Internet messaging. West Virginia changes only dealt with diagnosis or treatment by out-of-state physicians.

Questionnaires are widely used by Internet pharmacy Web sites. The Web-based questionnaire collects a health history and asks questions specific to the drug requested. Specific questions concerning requested drugs are usually based on information taken from the *Physicians' Desk Reference*. The completed questionnaire is then transmitted for approval by a physician licensed to practice medicine in the patient's home state. The process is the functional equivalent of in-office or telephone prescribing.

States scrutinize those who use the questionnaire prescription process because in some cases the "approval" is performed by physicians contracted by the pharmacies and those physicians have suspect licensure and may rubber-stamp rather than properly review prescriptions. In some cases, the

“approval” is omitted and the order is merely forwarded for fulfillment.

The most explicit attempt to control Internet prescribing is the implementation of a requirement of new and additional physical face-to-face examinations prior to prescribing. This requirement is designed to eliminate prescribing based on questionnaires.

Regulatory amendments to control Internet prescribing practices have also included provisions requiring in-state pharmacists to verify that the prescriptions presented to them are written after physical examinations. Some states prohibit a pharmacist from dispensing a prescription drug if he knows or should have known that the prescription was issued on the basis of an Internet-based consultation without a valid patient-practitioner relationship.

The state regulation of Internet dispensing is an extension of the state regulation of Internet prescribing. Typically, Internet medication facilitator sites pass an Internet user’s prescriptions for fulfillment to pharmacies. State law generally prohibits anyone in the chain of distribution from purchasing or receiving prescription drugs from anyone other than a licensed individual. State law combines physician regulation with the regulation of pharmacies through the traditional tools of licensure. While local pharmacists increasingly face regulation on their fulfillment of out-of-state prescriptions written by Internet-based physicians, it should be noted that states have successfully regulated pharmacy distribution located outside their borders for several decades.

State pharmacy law addressed issues concerning out-of-state pharmacies long before the growth of Internet prescribing. Mail-order dispensing is at least a century old and mail-order pharmacies are frequently subject to regulations in importing states.

The states have sought to extend their mail-order model of required licensure to interstate Internet prescribing. As with mail-order models, large e-pharmacies can obtain multiple licensures, for example, the Arkansas Internet Prescription Consumer Protection Act 2001 updates the traditional prohibitions on unlicensed dispensing to specifically include Internet operations.

The primary federal regulation that

governs prescription pharmaceuticals is the Food, Drug, and Cosmetic Act, which the Food and Drug Administration (FDA) is primarily responsible for enforcing. The act regulates distributors, including prescribing physicians.

States using their police power authority, which encompasses all matters that concern the health or welfare of its citizens, regulate certain aspects of physician and pharmacist practice. Specifically, states regulate licensing of prescribing physicians and pharmacists. With respect to Internet pharmacies, states have adopted statutes restricting any pharmacist from dispensing pharmaceuticals via the Internet.

U.S. Const. art. I, § 8 (Commerce Clause) grants Congress the power to regulate interstate commerce. *Gibbons v. Ogden*, 22 U.S. 1, 227 (1824), contains the first proffer that the Commerce Clause grants to the federal government all commerce regulation not specifically granted to the states. This finding is now known as the Dormant Commerce Clause.

The Dormant Commerce Clause prohibits state regulations in two ways. It prohibits state regulations that discriminate against interstate commerce and prohibits state regulations that, although nondiscriminatory in nature, impose an undue burden on interstate commerce.

While there have been several cases that have analyzed state regulations of pharmacy activity more generally under the Dormant Commerce Clause, such as *State v. Rasmussen*, 213 N.W.2d 661 (Iowa 1973) and *Pharm. Mfrs. Ass’n v. N.M. Bd. of Pharmacy*, 525 P.2d 931 (N.M. Ct. App. 1974), there has been no case law concerning the validity of state regulations of Internet pharmacies. There have been several cases concerning the validity of state regulations of Internet activity on a more general level, such as *PSINet, Inc. v. Chapman*, 167 F. Supp. 2d 878 (W.D. Va. 2001), *aff’d*, 362 F.3d 227 (4th Cir. 2004), which may be applicable to Internet pharmacies.

One line of cases suggests that state laws that regulate Internet activities necessarily violate the Dormant Commerce Clause. In *American Libraries Assn. v. Pataki*, 969 F. Supp. 160 (S.D. N.Y. 1997), the court used the Dormant Commerce Clause to invalidate a law that prohibited the communication of

certain types of sexually offensive material via the Internet. Several other federal courts that have considered the issue of Internet regulation have followed *Pataki*.

Another line of cases suggests that state regulations of Internet activities do not necessarily violate the Dormant Commerce Clause. In *Ford Motor Company v. Texas Department of Transportation*, 264 F.3d 493 (5th Cir. Aug. 27, 2001), a court upheld a state law that had been applied so as to prohibit the operation of an Internet Web site. Although the court upheld the regulation, it explicitly disapproved of the *Pataki* court’s blanket invalidation of all state regulations of Internet activity.

These two divergent lines of Internet cases are reconcilable. The Dormant Commerce Clause analysis requires a two-pronged inquiry: 1) whether the challenged regulation discriminates against out-of-state commerce; and 2) whether the challenged regulation poses an undue burden on interstate commerce. Thus, the *Ford Motor* case is technically correct and suggests *Pataki* should not have invalidated all state regulations of Internet activity without a showing that they are either discriminatory or unduly burdensome on interstate commerce.

In any case, the *Pataki* court’s finding is acceptable for interstate Internet transactions. Allowing the federal government to assume regulatory power when the pharmacy conducts business over the Internet represents an acceptable imposition of federal authority into an area traditionally regulated by the states.

Some state regulation of Internet pharmacies may survive Commerce Clause scrutiny. Nevada prohibits any Internet pharmacy that is not licensed and certified pursuant to Nevada regulations from dispensing a prescription to any Nevada resident. The requirements of the Nevada statute apply equally to both in-state and out-of-state Internet pharmacies and limits its reach only to transactions that involve Nevada residents. Therefore, the Nevada statute is likely nondiscriminatory, and thus passes the first prong of the Dormant Commerce Clause inquiry.

The Nevada statute provides significant local benefits by protecting the pub-

lic health and welfare from corrupt Internet pharmacists and dangerous prescription medications. The Nevada statute imposes only an inconsequential encumbrance on interstate commerce by requiring that Internet pharmacists obtain a Nevada license prior to doing business in the state. It is likely that the burden on interstate commerce will be outweighed by the local benefits; thus, the Nevada statute would also pass the second prong of the Dormant Commerce Clause analysis.

The New York statute, however, is not likely to satisfy the Dormant Commerce Clause since the requirements apply only to out-of-state pharmacies. New York requires all nonresi-

dent Internet pharmacists be licensed and in good standing in their state of residence, maintain available records of all shipments to the state of New York, and provide a toll-free telephone number at which the pharmacist can be reached. It is arguable that the statute operates in a facially discriminatory manner with the goal of deterring out-of-state business. Thus the statute is likely to be *per se* invalid.

The California statute is similarly unlikely to satisfy the Dormant Commerce Clause. The California statute requires that the pharmacist inquire as to a prior good faith physical examination before completing any transaction via the Internet. In practice,

this requirement, although perhaps useful, imposes an extremely onerous burden on Internet pharmacies by requiring that a pharmacist or another employee contact the prescribing physician to verify the validity of the prescription for each transaction. This requirement is even more daunting for the Internet pharmacy that is located out-of-state or perhaps even out of the country. The necessary effect of such a requirement would be to discourage Internet pharmacies from doing business in California. As such, the California statute imposes an undue burden on interstate commerce. Thus the statute is likely to be *per se* invalid. ■