

Comments regarding ecompetition

Introduction

On behalf of millions of American consumers and their health care providers, we welcome the timely opportunity to offer comments on consumer protection and practice competition in the context of business-to-consumer e-commerce.

We are nurse practitioners, graduate educated and clinically qualified to provide primary health care to consumers of all ages in all settings. Licensed to practice in every state and the District of Columbia, nurse practitioners (NPs) are board-certified in health care specialties ranging from neonatology to geriatrics. In accord with the laws of the states where they practice, NPs care for patients both independently and in collaboration with other health professionals. They write prescriptions in all but one jurisdiction of the United States. In 44 of these 50 jurisdictions, NPs are authorized to register with the DEA, thereby obtaining independent or plenary authority to prescribe controlled substances within the parameters determined by each state.

Approximately 95,000 health professionals in the United States have been educationally prepared as NPs.¹ Historically, NPs provide care to the underserved, the uninsured, and other consumers who experience multiple barriers in access to primary health services. As such, significant numbers of consumers cared for by NPs initially come to them in poor health. NPs traditionally and continuously have advocated not only for these patients in particular but also for all health care consumers, guided by a philosophy of practice based on preventive, educationally focused services delivered within a close patient-practitioner partnership.

One of the signatories to these comments is a board-certified NP in New York State with an independent pediatric practice of more than 5000 registered patients. The practice employs three other NPs and averages close to 10,000 documented office visits a year. Clinicians and staff alike provide bilingual primary health care services that are highly respected and valued by a culturally diverse community. Graduate NP and medical students receive precepted clinical education and experience in this challenging setting. The other signatory to these comments is a board-certified NP and doctor of public health in South Carolina whose pediatric practice serves a largely poor and underserved population, many of whom are uninsured. The practice also provides the only specialty child abuse care, including sexual assault evaluation, available in the community and surrounding region.

Background on the Current Situation

The underserved, the uninsured, and others who experience a spectrum of barriers in access to primary health care, many of whom present in poor health – in other words, the NP's core constituency – tend to suffer most acutely from the difficulties involved in receiving mail order/Internet pharmacy services. But even for NP patients without other

barriers to care, the obstacles can be formidable. Because of administrative provider discrimination in many states and lack of regulatory oversight of mail order/Internet pharmacies, consumers who are expressly directed by their health plans to use mail order/Internet pharmacy services are being denied those benefits. Hence, while it must be emphasized that the primary focus of these comments is the consumer, the potential for the consumer's plight to have secondary anticompetitive effects on NP practice cannot be ignored.

Whether insured or uninsured, the consumers for whom we advocate have chosen to have their primary health needs met by licensed, board-certified NPs who provide comprehensive patient-centered care, including the prescription of medications when needed. We especially advocate for those consumers who, because of circumstances of birth, educational preparation, socioeconomic circumstances, and health status, are less prepared or less able to advocate on their own behalf. We offer our comments to represent their concerns and to press for a more open process throughout the nation to permit the benefits of mail order/Internet pharmacies to inure to all health care consumers.

Specific Consumer Problems

As noted by experts in the area of Internet prescribing, online prescription drug sales "can provide tremendous benefits to consumers."² NPs agree. They also agree with the statement of the Federal Trade Commission (FTC) concerning its related workshop on health care and competition law: "Consumer/patient welfare is maximized by a health care system that efficiently delivers to Americans the services they desire."³

For consumers who desire the services of NPs, the part of the health care system that delivers medications through online and mail order prescription drug sales is proving to be far from efficient. In many instances, consumers have discovered that it does not deliver at all: within two weeks of sending out a request via a small NP listserv,

the authors of these comments received an outpouring of accounts from patients and practitioners alike on the barriers that consumers face in getting their prescriptions filled. The numbers of companies cited as denying patients' prescriptions were almost as varied as the numbers of reports themselves, but several major mail-order/Internet concerns that operate throughout the country and cover many millions of insured lives were singled out again and again as being particularly problematic.

Examples of patient reports:

- ♦ I followed my health plan's instructions on submitting prescriptions online. The medicines were so long in coming that I had to pay full price for a short supply from the local pharmacy to tide me over. Why? Because the Internet pharmacy refused to accept my NP's prescription, and sent it back.
- ♦ The bottle had a different doctor's name on the label, so I took it to my NP provider to tell her I had gotten the wrong medicine. I learned that the online pharmacy said a physician had to sign the prescription. Apparently, the pharmacist then made it the physician's order. I've never seen the physician. I didn't even recognize the name.

Examples of practitioner reports:

- ♦ The largest online pharmacy in the country constantly refuses to fill my patients' prescriptions unless they're co-signed by a "supervising physician." There are no "supervising physicians" for NPs in my state, so who would sign my orders? Since my prescriptions as written are already valid, what further validity would be gained even if I could find someone to co-sign? I'm independently licensed by the state nursing board to practice and prescribe. I'm board-certified in my practice specialty, and registered both with the federal DEA and the state controlled substances agency.
- ♦ The online pharmacy that denied my patient's prescription said that it had to follow the pharmacy law of the state where it dispensed, which, I was told, required a supervising physician's name for non-controlled prescriptions and the physician's signature on orders for scheduled meds. I looked up the pharmacy law in that state – it says nothing of the kind. Moreover, no law in the country requires a physician co-signature on any NP-written prescription.

Federal Guidelines, State Regulations, and Business Practices

Federal guidelines on dispensing prescription medications were reviewed through consultation with the Food and Drug Administration (FDA). In filling prescriptions, pharmacists are directed under FDA rules to adhere to both the state law that governs the prescriber's authority to prescribe and the state law that governs the pharmacist's authority to dispense. Thus, if prescribers transmitting prescriptions are authorized to prescribe the particular medications in the states where they are licensed, and receiving pharmacists are not prohibited from dispensing them in the states where they are licensed, it should be expected under federal rules that such prescriptions will be filled.

A sampling of state pharmacy laws around the country were also reviewed, revealing only one in which explicit limitations are placed on pharmacists in filling out-of-state prescriptions. Under Texas pharmacy regulations, an out-of-state prescription is honored to the extent that the prescriber is "a person licensed by another state in a health field in which, under Texas law, licensees in this state may legally prescribe dangerous drugs..."⁴ In Texas, then, an out-of-state prescriber's authority to prescribe is subsumed under the authority of an equivalent in-state prescriber to prescribe.

Of the major mail-order/Internet pharmacies that have been repeatedly troublesome for consumers, at least one appears to have adopted Texas-style law to defend its denial of consumers' prescriptions written by out-of-state NPs. The New Jersey-based company states that, under New Jersey pharmacy law, such prescriptions must comply with the prescribing regulations that govern NPs licensed in New Jersey. In fact, there is no language in New Jersey pharmacy law requiring compliance with in-state NP prescribing law. Rather, pharmacists under New Jersey law have the right to refuse a prescription that is "outside the prescriber's scope of practice"⁵ – *the* prescriber, not an equivalent New Jersey prescriber. By all accepted definitions, *the* prescriber is the one who writes the prescription.

In contrast to pharmacy regulations in Texas, business practices in New Jersey, and other similar company policies as reported by practitioners and patients, Ohio pharmacy law has articulated a close adherence to the FDA guidelines that is both pro-consumer and pro-competition. Under Ohio law, “A non-resident prescriber whose license is current and in good standing and who is authorized to issue prescriptions for drugs in the course of professional practice in a state other than Ohio is authorized to write prescriptions in that state for drugs to be dispensed in the state of Ohio.”^{6 7}

Consumer Protection and Fair Competition

In published testimony on mail order/Internet prescribing, both the FTC and FDA have cited the pro-consumer qualities inherent in a patient-practitioner relationship that is comprised of periodic physical examination, prescriber familiarity with current health status, and adequate review of the consumer’s medical history.^{8 9} NPs agree. It is exactly this relationship that forms the foundation of all NP patient-care decisions, including the decision to prescribe medications as legally authorized in the jurisdiction in which the NP is licensed. It logically follows, then, that having someone who may never have examined or even known the patient sign the patient’s prescription does nothing to further consumer protection. In fact, such a business practice compromises the essence of the patient-practitioner relationship. It also delays the delivery of needed medications, which in turn increases patient morbidity risk.

Without basis in either pharmacy or prescriber law, restrictive business policies and discriminatory administrative practices will lead to an undermining of the very patient-practitioner relationship that the agencies uphold. If consumers keep finding themselves barred from having their prescriptive needs fully met under NP care – no matter how good that care is otherwise – they will have to seek out other providers who are not so constrained by unfounded policies and practices. These actions, therefore, are not only less protective of consumer welfare but also anticompetitive.

Specific FTC Issues Addressed by the Workshop¹⁰

- ♦ “What types of state regulations limit online provision of health care goods and services?”

State pharmacy regulations such as those in Texas severely limit the ability of out-of-state consumers to access online pharmacy services that are based in states where NP prescribing laws are more narrowly drawn than in the consumers’ states. Additionally, the lack of clearly expressed protection of consumers’ rights to access these services, such as Ohio incorporates, leaves businesses like the one in New Jersey free to make up their own rules that discriminate against certain consumers, restrain trade, and restrict legitimate interstate commerce.

- ♦ “What are the costs to consumers?”

The costs of unnecessarily restrictive regulations and policies are not precisely known, but anecdotal evidence indicates that they are high. In addition to the consumers who are forced to pay out of pocket for interim medications while they wait and wait for their mail order/Internet prescriptions to arrive, many consumers bear the full weight of all

their prescriptions because they elect to stay with the NPs whose care they value more than their health plan's drug coverage. As noted in the introduction to these comments, approximately 95,000 NPs are currently recognized by boards of nursing in the United States. A recent survey across a comprehensive range of practice specialties showed that NPs write almost 9.8 million prescriptions per month.¹¹ Based on these figures, the average number of prescriptions written each year by an individual NP is more than 4,200. With increasing numbers of contract arrangements between health insurance plans and mail-order/Internet pharmacy services, clearly the costs of denial – in terms of both dollars and health – will increase proportionately.

- ♦ “What are the pro-consumer rationales for regulations, and are there less restrictive means of achieving the same goals?”

From the practitioner perspective, there are no pro-consumer rationales for regulations or business practices that unduly hinder access to legitimate health services that consumers need and desire. Consumers choosing NPs as their primary care providers are well protected by the licensing and certification standards of the states in which their NP providers practice. Consumer protection goals have already been achieved by these means as well as by rigorous NP educational requirements, all of which continue to ensure a highly safe, effective level of care. If *anything* is needed, it is a relaxation of the outdated regulations that still restrict the ability of NPs to provide for patients to the full extent of their education, knowledge, and proven skill. That move would be truly pro-consumer.

- ♦ “Are reciprocity statutes an effective way to deal with these issues?”

Reciprocity statutes undoubtedly would help unblock the barriers that consumers face in accessing mail order/online pharmacy services. Legislation, however, is a long process, and in the meantime, consumers are being shut out of the new marketplace without justification. A more expedient and efficient solution would be regulatory changes such as the incorporation of rules like Ohio's into all state administrative codes. The FTC and FDA should support the adoption of such rules in the interests of consumer protection and fair competition. Finally, the FTC should provide leadership in applying to the diverse community of NP, MD, DO, and PA health professionals the same doctrine that the agency articulated in Connecticut this year: the belief that consumer welfare can be maximized “by following the most pro-competitive approach consistent with the protection of consumers' health.”¹²

Respectfully Submitted,

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- ¹ Kelly/Waldron & Associates. Nurse practitioner prescribing data profile. August 2002.
- ² Woodcock J. Prepared Statement of the Federal Trade Commission on “Drugstores on the Net: The Risks and Benefits of Online Pharmacies.” Before the Subcommittee on Oversight and Investigations of the Committee on Commerce, United States House of Representatives, Washington, DC; July 30,1999.
- ³ Federal Trade Commission. Federal Register Notice. Public Workshop: Health Care and Competition Law and Policy; July 10, 2002.
- ⁴ Texas Administrative Code. Pharmacy regulations. Title 22, Part 15, Chapter 291, Subchapter B38(b).
- ⁵ New Jersey Administrative Code. Pharmacy regulations. Title 13, Chapter 39, Subchapter 6.1(a).
- ⁶ Ohio Administrative Code. Pharmacy regulations. 4729-5-15(c).
- ⁷ New Hampshire has also adopted a pro-consumer, pro-competition position: the New Hampshire Board of Pharmacy states that mail-order/online pharmacies located in NH may dispense prescriptions written by an out-of-state NP (for an out-of-state patient) provided that the prescriber is licensed in the domiciled state and that the prescription would be deemed legal to fill in the state of domicile. (Personal communication, August 2002).
- ⁸ Bernstein J. Prepared Statement of the Federal Trade Commission on “Drugstores on the Net: The Risks and Benefits of Online Pharmacies.” Before the Subcommittee on Oversight and Investigations of the Committee on Commerce, United States House of Representatives, Washington, DC; July 30,1999.
- ⁹ Woodcock J., 1999.
- ¹⁰ Federal Trade Commission. Federal Register Notice. Public Workshop: Possible Anticompetitive Efforts to Restrict Competition on the Internet; July 17, 2002.
- ¹¹ Kelly/Waldron & Associates. Monthly prescription reports. August 2002.
- ¹² Federal Trade Commission. Intervenor Comments in re: Declaratory Ruling Proceeding on the Interpretation and Applicability of Various Statutes and Regulations Concerning the Sale of Contact Lenses. State of Connecticut, Department of Public Health & Connecticut Board of Examiners for Opticians; March 27, 2002.